Section V
General Policies, Procedures & Guidelines

PROVIDER MANUAL
FOR
COMMUNITY MENTAL HEALTH,
DEVELOPMENTAL DISABILITIES AND
ADDICTIVE DISEASES
PROVIDERS
UNDER CONTRACT WITH
THE DIVISION OF MENTAL HEALTH,
DEVELOPMENTAL DISABILITIES AND ADDICTIVE DISEASES

DHR
JULY 2005

CONTRACTING AND SUBCONTRACTING BY CONTRACTOR

Required Approvals

A. As specified in Paragraph 116, page 8 of the contract, the Division's approval is not required of the Contractor to enter into a subcontract for services specified in the contract. The Contractor must provide the Regional Office a copy of the original subcontract and any contract amendments in their entirety no later than thirty (30) days after the effective date of the subcontract accompanied by the ***Contract Transmittal Form*** (included within the Appendices for this section).

Contents of Subcontracts

A. Any subcontracts of the Contractor will be in writing and clearly state the service or product being acquired through said subcontract with a detailed description of cost.
B. Any subcontracts of the Contractor for the provision of consumer services and/or operational services addressed in whole or in part by the Provider Manual will incorporate a certification to be signed by the subcontractor indicating the subcontractor has received and will comply with the Provider Manual.
C. Any subcontracts by the Contractor will require subcontractors to comply with all provisions of the federal and state laws, rules, regulations and policies.

Responsibility For Subcontractor's Performance

As specified in the contract, the contractor agrees to be responsible for the subcontractor's performance and compliance with applicable provision of the contract and the Provider Manual. The Contractor will ensure that the subcontractor both understands and abides by all pertinent provisions of the contract, the Provider Manual and any regulations applicable to the subcontractor. The contractor also must ensure that the subcontractor receives the Provider Manual and all revisions to the Provider Manual.

Non-Delegation of MHMRIS Reporting Responsibilities

While a primary contractor (Provider A) can subcontract with a secondary entity (Provider B) to meet some of Provider A's contracted obligations, the primary contractor retains responsibility for reporting to the Statewide Community Information System, MHMRIS.

- Provider A must **not** relinquish responsibility for reporting to MHMRIS. Contract compliance will require that the subcontractor, Provider B, submit data to the contractor, Provider A, who will in turn submit data to MHMRIS. However, for PERMES purposes, providers may delegate their responsibility for reporting to PERMES, assuming they use contractor facility ID.
- This also means that a subcontractor should not have a Facility/Unit/ Subunit designation in MHMRIS for activities conducted as a subcontractor.

Compliance with State's Minority Business Policy

Contractors who by virtue of their contract with the MHDDAD/Regional Office are allowed to subcontract will follow the State's Minority Business policy. The policy of the State of Georgia is that minority business enterprises shall have a fair and equal opportunity to

participate in the purchasing process. The State encourages all companies to subcontract portions of any State contract to minority business enterprises.

INSURANCE REQUIREMENTS

I. Requirements Applicable to Public Providers (e.g., Community Service Boards and County Boards of Health) The following shall be adhered to by public providers throughout the term of the contract, any renewal thereof, and as otherwise specified herein:

A. Insurance Certificate: The Provider shall procure and maintain insurance which shall protect the Provider and the State from any claims for bodily injury, property damage, or personal injury which may arise out of operations under the Contract. The Provider shall procure the insurance policies at the Provider's own expense and shall furnish the State an insurance certificate listing the State as certificate holder. The insurance certificate must document that the liability insurance coverage purchased by the Provider includes contractual liability coverage to protect the State. In addition, the insurance certificate must provide the following information:

1. Name and address of authorized agent,
2. Name and address of insured,
3. Name of insurance company (licensed to operate in Georgia),
4. Description of coverage in standard terminology,
5. Policy period,
6. Limits of liability,
7. Name and address of certificate holder,
8. Acknowledgment of notice of cancellation to the State,
9. Signature of authorized agent,
10 Telephone number of authorized agent,
11. Details of policy exclusions in comment section of Insurance Certificate.

B. The Provider also agrees to adopt a resolution requesting D.O.A.S. to provide insurance coverage to document that the following types of insurance coverage have been purchased by the Provider :

1. Workers' Compensation Insurance

To insure the statutory limits as established by the General Assembly of the State of Georgia (NOTE: A self-insurer must submit a certificate from the Georgia State Board of Workers' compensation stating the Provider qualifies to pay its own workers' compensation claims.) The Workers' Compensation Policy must include Coverage B - Employer's Liability Limits of:

Bodily Injury by Accident -	$ 500,000 each accident
Bodily Injury by disease -	$ 500,000 each employee
	$1,000,000 policy limits

Provider shall require all Subcontractors performing work under this Contract to obtain an insurance certificate showing proof of Workers' Compensation Coverage.

2. Commercial General Liability Policy:*
Combined Single Limits: $1,000,000 per person
$3,000,000 per occurrence

The Commercial General Liability Policy must insure provider's officers, board members and employees in their individual capacities and must be on an "occurrence" basis.
*A Comprehensive General Liability Policy may be substituted for the Commercial General Liability Policy if the Comprehensive General Liability Policy has been endorsed to insure contractual liability, broad form property damage, and personal injury liability.

3. Business Automobile Liability Policy:
Combined Single Limits: $1,000,000 per Person
$3,000,000 per Occurrence

All policies must be on an "occurrence" basis, unless expressly otherwise stated.

C. The foregoing policies shall contain a provision that coverage will not be canceled or allowed to lapse until at least thirty (30) days prior written notice has been given to DHR. Certificates of Insurance showing such coverage to be in force, or a resolution requesting D.O.A.S. to assist in the purchase, shall be filed with DHR prior to commencement of any work under this Contract. The foregoing policies shall be obtained from D.O.A.S. (with the consent and approval of D.O.A.S.) or insurance companies licensed to do business in Georgia and acceptable to DHR. Evidence of insurability under these provisions shall be directed to the Department's Office of Support Services. It shall be the responsibility of the Provider to require any Subcontractor to indemnify and hold harmless the Regional Office, Regional Planning Board, the Division, DHR and the State; to secure insurance coverage sufficient to cover possible liability, and to obtain a certificate or certificates evidencing that such insurance is in effect. In addition, the Provider shall indemnify and hold harmless the Regional Office, Regional Planning Board, the Division, DHR and the State from any liability arising out of the Provider's or Subcontractor's untimely failure to secure adequate insurance coverage as prescribed herein. All such coverage shall remain in full force and affect during the initial term of the Contract and any renewal or extension thereof.

D. At the request of the Department's Office of Support Services, the Provider will supply all necessary underwriting data for the purchase of insurance coverage through the Department of Administrative Services

(D.O.A.S.), including workers' compensation, unemployment insurance, general liability, vehicle liability, fidelity bond and property insurance. The Provider will remit in a timely manner required premiums for vehicle liability and fidelity bond insurance to the Department Office of Support Services.

E. For insurance coverage provided by the D.O.A.S., the D.O.A.S. shall have the authority to examine and copy any records of the Provider to facilitate the investigation of any claim covered by such insurance. The Provider shall make available to D.O.A.S. all such records incidental to any investigation of a claim notwithstanding any other provisions of law which designates such records as confidential or which prohibits disclosure of such records; provided, that D.O.A.S. shall be bound by such provisions of law and shall not make further disclosure of such records.

II. Requirements Applicable to Private Providers The following shall be adhered to by private provides throughout the term of the contract, any renewal thereof, and as otherwise specified herein:

A. Insurance Certificate: The Contractor shall, at its expense, procure a Commercial General Liability Insurance Policy, including personal and advertising liability (or a Comprehensive General Liability Policy) with endorsement to insure contractual liability, broad form property damage, personal injury, personal and advertising liability, and other insurance policies in coverage amounts of $3 million per occurrence and $1 million per person, with endorsement waiving right of subrogation against the State, the Indemnities, the Fund and insurers participating thereunder.

B. Fidelity Assurance Bonds: Private Non-Profit Contractors who are requesting an advance of funds under the contract MUST be bonded. The bond may be a blanket bond covering all contract positions, or it may be a position bond, listing specific positions. If a position bond is used, each position scheduled must be for the minimum amount required. While it is customary to list the chief executive officer on the bond, the bond must cover anyone handling funds or authorizing expenditures. The bond must be made payable to the State of Georgia, Department of Human Resources or payable jointly to the Contractor and DHR. If the Contractor has a very large bond covering its entire operation, it can assign, through an endorsement or rider, the required portion of the bond to DHR.
The bond amount is determined by calculating the total amount of the contract (total amount is inclusive of local match, donor funds, in-kind match, certified costs, certified public expenditure, certified cash transfers, budgeted State and Federal funds) by the percentage listed below and comparing that to the amount of the advance. The larger of the two figures must be the amount of the bond. The Contractor will submit to the Regional Board a binder, certificate of insurance or a copy of the bond. If a binder letter is used, the binder must include the name of the bonding company, bond number, period of coverage, amount of coverage, who is covered, and statement that the bond is payable to DHR or jointly payable to DHR and the Contractor.

II. Fidelity/Assurance Bond Schedule

Total Contract Budget	Amount of Bond
up to $50,000	25%
$50,000 to 54,999	24%
$55,000 to 59,999	23%
$60,000 to 64,999	22%

$65,000 to 69,999	21%
$70,000 to 74,999	20%
$75,000 to 79,999	19%
$80,000 to 84,999	18%
$85,000 to 89,999	17%
$90,000 to 94,999	16%
$95,000 to 99,999	15%
$100,000 to 199,999	14%
$200,000 to 399,999	13%
$400,000 and up	12%

CRIMINAL RECORDS INVESTIGATIONS

I. REQUIREMENTS

A. As stated in the contract, the Contractor agrees that, for the filling of positions or classes of positions having direct care/treatment/custodial responsibilities for services rendered under this contract, existing employees and applicants selected for such positions shall undergo a criminal record history investigation which shall include a finger print record check pursuant to the provision of Section 49-2-14 of the Official Code of Georgia Annotated.

B. The Contractor further agrees that all volunteers having direct care/treatment/custodial responsibilities of consumers shall undergo a criminal record history investigation which shall include a fingerprint record check.

C. The contract further specifies that Criminal Records Investigations do not apply to persons employed in day-care center, group day-care homes, family day-care homes, or child-caring institutions which are required to be licensed or registered by the Department or to personal care homes required to be licensed, permitted or registered by the Department.

II. PROCEDURE

Obtaining Applicant Fingerprint Cards

Applicant Fingerprint Cards must be obtained from the Office of Investigative Services by sending a written request for the forms to the address listed below. The request should include the number of forms needed (It is recommended that at least a 3 month supply be ordered) and the address of the provider/contractor to which the forms are to be sent. The written request should be sent to:

Office of Investigative Services
Attn: Dawn Braxton
2 Peachtree Street, NW, Room 23.282
Atlanta, Ga. 30303-3182

Only an original Applicant Fingerprint Card obtained from the OIS is to be used by contractors. A unique identifier code on these forms is used by the Georgia Crime Information Center to return the information to the proper authority that, in this case, is the Department of Human Resources.

Obtaining Required Information

1. The contractor shall require that each applicant for employment, each person employed pending a Criminal Records Investigation, or volunteer shall complete and submit to the contractor a ***Consent for Release of Information***, a copy of which is included within the Appendices to this section.

2. The contractor should complete two Applicant Fingerprint Cards with all applicable information requested on front side of the Applicant Fingerprint Card and proper sets of fingerprints on each employee/applicant/volunteer following the instructions

contained on the back of the card. Contractors may make arrangement with local law enforcement agencies to perform the fingerprinting.

Transmitting Applicant Fingerprint Cards to Georgia Crime Information Center (GCIC)

The contractor is responsible for transmitting directly to the Georgia Crime Information Center (GCIC) two originals of the cards for each employee/applicant/volunteer to the address listed below. The cards must be accompanied by the required processing fees which are payable by agency check or money order to the Georgia Bureau of Investigation. Fee requirements may be verified by calling the GCIC automated applicant information line (404-244-2881).

Georgia Crime Information Center
Attn: AFIS Applicant Section
Post Office Box 370748
Decatur, Georgia 30037-0748

GCIC will forward one of the completed fingerprint cards to the Federal Bureau of Investigations (FBI) for the fingerprints to be checked for a criminal record nationwide. The second fingerprint card is processed by GCIC to check for a criminal record in the State of Georgia. **Fingerprint cards should <u>not</u> be folded for mailing.**

Terminating or Withdrawing Offers of Employment or Volunteer Status Based on Review of Criminal Records.

After receiving the information from the GCIC or any other appropriate source, the Department's Office of Human Resource Development will review any derogatory information. If the crime is one which requires disqualification from employment in accordance with duly published criteria within the Department, the Department will inform the contractor, and the individual so identified will not be employed for the purpose of providing services under this contract or if they were employed prior to the completion of the background check for purposes of providing services under this contract, the contractor will terminate the individual's employment. In the case of volunteers, the Department will review any derogatory information based on the same criteria published for employees and, if the crime is one which requires disqualification, the Contractor will be informed, and the individual as identified will not be allowed to provide direct care/treatment/custodial care of consumers. Access to the DHR policy Number 504 on Criminal History Records may be obtained through http://www2.state.ga.us/departments/dhr/ohrm.html and choosing the link "HR\Personnel Policies".

CONFIDENTIALITY

I. Legal References

21 CFR § 1175, O.C.G.A. §§ 24-9-21; 26-5-17: 37-3-166; 37-4-125; 37-7-166; 37-2-1.2; 43-39-16.

To respect and acknowledge the privacy and confidentiality of consumers is the responsibility of all who participate in the delivery of services to the disabled. Confidential consumer information contained in records, charts, documents or other forms of recordation may be released only on a need to know basis to persons authorized by law or upon written consent of the consumer. Furthermore, it is advisable that consumer information not be discussed openly, other than is necessary to benefit the consumer, and only among duly authorized staff or others clearly involved in the care of the consumer.

II. Confidential Information

Need to know information includes, but is not limited to, information used to:

A. Determine eligibility
B. Provide treatment for, or contribute to, the diagnosis of any medical or psychological illness, injury, or condition
C. Assess financial liability
D. Pay any financial obligations
E. Initiate or further any investigatory, regulatory, or enforcement purpose
F. Provide service

III. Considerations

To meet the needs of consumer's in an efficient, effective way, and to accomplish the goal of simplifying access to services, contractors may share consumer information on a need to know basis across provider/program lines unless prohibited by state or federal law. The disclosure of consumer information shall be guided as follows:

A. Contractors shall respect and acknowledge the privacy rights of consumers.
B. Only those persons with proper authorization may access confidential consumer information.
C. Consumers shall be informed that information and records may be shared with authorized persons.
D. Contractors shall be responsible for handling and safeguarding consumer records to protect their confidentiality.

IV. Sharing Consumer Information

A. Contractors may share consumer information within its organization on a need to know basis in furtherance of consumer's treatment or programmatic goals.

B. Policies and procedures should be established for determining which employees shall have access to different types of consumer information.

C. Contractors should develop a procedure for handling requests for consumer information from outside its organization.

V. Clinical Records

Perhaps the greatest source of confidential consumer information is the consumer's clinical records. These records are afforded specific protections under the law and must be handled in a manner designed to meet the law's requirements. Providers are urged to consult O.C.G.A. § 37-3-166 (MH); 37-4-125 (MR) and 37-7-166 (SA), to determine when such clinical information may be disclosed. A thorough reading of the applicable statute and/or legal consultation is urged when there is uncertainty regarding the disclosure of consumer information to anyone not directly involved in their treatment.

VI. Unauthorized Disclosure of Consumer Information

Georgia Law and Federal Regulations protect the consumer's right to confidentiality. Any violation of the consumer's right to confidentiality may subject the party or parties responsible for the unauthorized disclosure to statutory penalties and/or civil action.

	Department of Human Resources **Directives Information System**	**Index: POL7901** **Revised: 2/09/00** **Review: 2/01/02** **Page 1 of 3**

SUBJECT: Protection of Human Subjects

POLICY

The policy of the Department of Human Resources is to assure the protection of the rights of human subjects in research activities that are conducted in association with the Department. The Department will assure subjects' rights by following the policies and procedures contained in 45 CFR, Part 46, Protection of Human Subjects; 21 CFR, Part 50, Protection of Human Subjects; and 21 CFR, Part 56, Institutional Review Boards. The Department is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled: The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. A Departmental sponsor is designated when the research is not conducted by an agent of the Department.

A. Authority

45 CFR, Part 46, AProtection of Human Subjects
21 CFR, Part 50, AProtection of Human Subjects
21 CFR, Part 56, AInstitutional Review Boards

B. References

O.C.G.A. ə 50-18-101 AUse of Confidential, Classified, or Restricted Records for Research, Limitations
DHR Directive AConfidentiality of and Access to Records

C. Applicability

This policy and related procedures apply to research that is conducted either by the Department or is sponsored by the Department and involves human subjects. Applicability is not limited to federally sponsored projects.

D. Definitions

Research ≅ means a systematic investigation designed to develop or contribute to generalized knowledge. Routine program evaluation is excluded under this definition.
Human subject≅ means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information.
Identifiable private information≅ means any information about an individual's behavior that: occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, **or** has been provided for specific purposes and which the

individual can reasonably expect not to be made public (e.g., a medical record), **and** the information is individually identifiable (i.e., the identity of the individual is or may be ascertained by the investigator or associated with the information).

Conducted by the Department≅ means any research activity that is conducted by an employee of the Department or is funded by the Department.

Sponsored by the Department≅ means any research activity which requires the support of the Department for granting access to subjects or information. A sponsor is an employee of the Department who assumes certain responsibilities for a research project.

E. Responsibilities

1. It is the responsibility of the Commissioner to establish and maintain an Institutional Review Board that is competent to assure the protection of the rights of human subjects by appointing members according to the policies listed in 45 CFR, Part 46.107, AIRB Membership. Each member will receive orientation to the Board and will participate in a program of continuing education to maintain skills and knowledge. Each member's home division/office is responsible for supporting the activities of the appointed member.
2. It is the responsibility of the Director of the Office of Regulatory Services to provide staff support to the Board by appointing an Executive Secretary and by supporting the activities of that position.
3. It is the responsibility of the DHR Institutional Review Board to assure the rights of human subjects by following the policies and procedures written in 45 CFR, Part 46; and 21 CFR, Parts 50 & 56.
4. It is the responsibility of each division and office to ensure that all research involving human subjects conducted or sponsored by the division/office is approved by the DHR Institutional Review Board. When the research involves access to confidential information and is conducted by a departmental employee or agent, the investigator's division or office is responsible for following the provisions indicated in laws, rules, regulations, etc., concerning access to and release of the information held in confidence.
5. It is the responsibility of the Board to issue procedures (PRO7901) to implement this policy. The procedures include a manual: AGuidance to Researchers Using Human Subjects (MAN7901).
6. It is the responsibility of the researcher to follow the procedures contained in the manual: A Guidance to Researchers Using Human Subjects.
7. It is the responsibility of the departmental sponsor to assure that the research project does not have a negative impact on the provision of service that is being offered. The sponsor is aware of problems and adverse findings during the conduct of the project and apprises the Board of these events. When the research involves access to confidential information, the sponsor assures that all provisions of applicable laws, rules, regulations, etc. are followed concerning the release of and access to the confidential information.

F. History

Revision of Georgia Department of Human Resources Policy, A Protection of Human Subjects, POL7901, effective 9/30/98.

G. Evaluation

The assurance of rights of human subjects of research conducted by or sponsored by the Department is evaluated by the following methods:

1. On-site assessments are made by DHR staff. When the principal investigator of a project is not a DHR employee and the Board feels that there is significant risks to subjects, the DHR sponsor may be requested to perform an on-site assessment of the project. At other times, Board members may randomly select projects for scheduled or unannounced review. A written summary of these visits is kept for three years.
2. The FDA periodically performs an on-site survey of compliance with federal regulations. Reports of these surveys are kept on file for three years.
2. An annual review is performed each March to assess any reports from departmental sponsors, any report of breaches of confidentiality, adverse events, or complaints. At the same time, a management information summary is compiled by the executive secretary of actions by the Board for the previous 12 months, including a report of timeliness of actions.

H. Authentication

_____Audrey W. Horne_____ _____2/9/00_____

Commissioner Date

	Department of Human Resources **Directives Information System**	**Index: PRO7901** **Revised: 10/1/2000** **Review: 10/1/2002** **Page 1 of 3**

SUBJECT: Protection of Human Subjects

PROCEDURE

1. Institutional Review Board:

1.1. Board membership

The Review Board consists of at least eight members with varying backgrounds to promote complete and adequate review of research activities conducted or sponsored by the department. Members are appointed to meet the following representative criteria: a) two medical doctors who have training and experience in a medical field sufficient to be able to assess medical risks; b) a person who has training and experience in the conduct of scientific investigations; c) a person whose primary concern is not in the area of scientific investigation; d) a legal professional who has experience with the types of issues confronted by the Department and its consumers; e) a person who is not, and whose immediate family is not, affiliated with the Department except as a member of this Board; and, f) a person who has training and experience in working with the consumers of the Department. Additionally, the Board should include diverse membership with regard to race, gender, and cultural backgrounds and shall include persons knowledgeable of institutional commitments and regulations and standards of professional conduct and practice.

Members are nominated by Division/Office Directors and appointed by the Commissioner for staggered two-year terms. Alternate members may be appointed. Alternates are nominated and appointed in the same manner as primary members and serve two-year-terms. They have the same representative capacity as primary members for whom they serve as alternates. An alternate member cannot replace a primary member at a convened meeting unless he/she has received and reviewed the same material that the primary member has received or would have received. An alternate has no vote if the member for whom they are an alternate is present.

There is a chairperson and vice-chairperson who are elected by the members of the Review Board for a term of two years. A representative from the Department's Office of Regulatory Services serves as permanent Executive Secretary of the Board.

1.2. Meetings of the Board

Meetings of the Review Board are scheduled to ensure timely review of all projects. A majority of the membership constitutes a quorum, including at least one member whose primary concerns are in the nonscientific area. A majority vote is required for approval of a motion. If a quorum is interrupted during the proceedings, actions on studies are suspended until a quorum is again attained. All projects approved using the expedited review process are included on the agenda of the next convened meeting of the Board. Votes are recorded and reported numerically. Meetings are public and open to any interested party. Information regarding time and location of meetings may be obtained from the Executive Secretary.

1.3. Functions of Chairperson

The Chairperson, the Vice-Chairperson, or a designee presides at all convened meetings of the Board. Additionally, the Chairperson is responsible for:

a. reviewing all applications and determining (with the Review Coordinator) if they meet the criteria for approval without detailed review or for expedited review;
b. assigning a Review Coordinator for each project to be reviewed;
c. reviewing and approving agenda prior to meetings of the Board;
d. providing members with available information to assist them in carrying out the functions of the Board;
e. assuring that members have background and training to assure competent functioning of the Board; and,
f. serving as a liaison between the Board and the Office of Human Research Protections, the Food and Drug Administration, and other Federal Agencies.

1.4. Functions of the Review Coordinator

After the Chairperson performs a cursory review of an application, he or she assigns it to a Board member who serves as the Review Coordinator for the project until it is closed by the Board. The Chairperson makes a recommendation regarding the type of review (see section 4.1. of the manual MAN7901). If the Review Coordinator disagrees with the recommended type of review, he or she contacts the chairperson and they resolve the issue. The Review Coordinator is responsible for a detailed initial review, for communication with the investigators, and for tracking the project until it is closed. Specifically, the responsibilities are:

a. upon receipt of the application, performs a detailed review to identify issues, missing information, unanswered questions, or other needed information;
b. contacts the investigator, prior to application being placed on the agenda, to resolve the identified issues, missing information, etc.
c. notifies the chairperson when the application is ready to be placed on the meeting agenda;
d. presents the application at the convened meeting of the Board; (The presentation generally lasts a maximum of 5 minutes and identifies, at a minimum: (1) the involvement of DHR, (2) the purpose and design of the study, (4) subject information - vulnerable, how many, where, how recruited, etc., and, (5) issues for discussion.)
e. after the Board members discuss the issues, including any other issues identified by other Board members, recommends a decision to either table the application, approve it with conditions, or approve it with no conditions;
f. writes a detailed description of the presentation, discussion, and decisions made at the Board meeting regarding the application and forwards the description to the Executive Secretary and Chairperson within two working days of the meeting;
g. receives (from the Executive secretary) all correspondence regarding the project and responds appropriately;
h. co-signs with the Executive Secretary, all correspondence regarding the project;
i. oversees the continuing review process including timely notification of the investigators, and functions a, b, c, d, e, and f, stated above, as they relate to the continuing review.

1.5. Functions of the Executive Secretary

The Executive Secretary is responsible for:

a. providing necessary staff assistance, and making recommendations to the chairperson;
b. in conjunction with the Review Coordinators, receiving and issuing all communications with applicants;
c. in conjunction with the Review Coordinators, recording and publishing minutes of the meetings of the Board;
d. communicating with Board members, including scheduling meetings;
e. maintaining records;
f. in conjunction with the Review Coordinators, insuring timely continuing reviews of all projects, including notifying investigators when reports are due;
g. maintaining the “Project Status Form” for each project and the associated database; and,
h. assuring that a quorum is met and maintained throughout the proceedings at all convened meetings of the Board.

1.5. Record Keeping

The Executive Secretary maintains adequate documentation of the Board's activities, including the following:

a. copies of applications reviewed, including all attachments, progress reports submitted by investigators, statements of significant new findings provided to subjects, and reports of adverse events;
b. minutes of IRB meetings which are sufficient in detail to show attendance at meetings, actions taken by the IRB, the vote tally on all actions, the basis for requiring changes in or for disapproving applications, and a written summary of discussion of issues and their resolution;
c. records of continuing review activities;
d. copies of all correspondence; and,
e. a list of Board members identified by name, earned degrees, representative capacity, indications of experience sufficient to describe each member's chief anticipated contributions to Board deliberations, and a description of each member's affiliation with the Department.

These records are retained for at least three years, except that all records related to research that is conducted will be kept for at least three years after the completion of the research project.
These records are available for inspection and copying by authorized persons during normal business hours. They are housed in the Office of Regulatory Services.

2. Auxiliary Review Committees

Institutions or divisions within the Department which conduct or support a significant amount of research may elect to form an internal committee for oversight of research activities within their organizational unit. The functions of any internal committee may supplement the functions and responsibilities of the Department's Institutional Review Board, but will not be a substitute for any required activities of the Board.

3. Application for Approval and Guidance to Researchers

This information is contained in the "Guidance to Researchers Using Human Subjects Manual." See attached Manual, Directive # MAN7901.

A. History

Replaces PRO7901, effective date of 9/30/1998.

B. Proponency

Office of Regulatory Services
Executive Secretary of the IRB
Phone: (404) 657-5700

C. Attachments:

1. Continuing Review Form
2. Project Status Form

IRB Study Number_____

2 Peachtree Street, NW, Suite 32-415
Atlanta, GA 30303-3167
(404) 657-5700

CONTINUING REVIEW FORM

Title of Research:

_____

_____

_____

_____

Approval Period: From_____ To_____

(**NOTE**: Any data collected before the approval date or after the end date shown above is not covered by IRB approval. If the project is not completed by the end date, this form must be completed and submitted to the Board in order to receive continuing approval for the project. The form must be received by the Board **at least six weeks prior to the end date** in order to assure uninterrupted approval. Complete this form at the conclusion of the project and send it to the IRB)

1. What is the stage of the project? (Circle One)
   a. Initial preparation
   b. Data Collection
   c. No further involvement with subjects

2. Have any subjects dropped out or been withdrawn from the study?
   YES NO (If yes, attach explanation.)

3. Since the project was approved, have all changes been submitted to the Board for review and approved?
   YES NO (If no, project activities must stop until approval is granted.)

4. Attach to this form a summary description of the experiences of subjects who have been involved with the project. Include information about benefits, adverse events, problems, and complaints, and any results to date.

5. Have all approved procedures been followed?
   YES NO (If no, attach an explanation.)

6. Has the project resulted in any risks to subjects that were not identified in the approved protocol?
   YES NO (If yes, attach an explanation.)

7. Is there any further information that should be communicated to the Board?
   YES NO (If yes, attach communication.)

8. Please attach a copy of the consent form that you are currently using.

This completed form and its attachments are an accurate report of the progress and status of the project.

_____ _____

Signature of Investigator Date Signature of Sponsor Date

DHR Institutional Review Board
Number_____
2 Peachtree Street, NW, Suite 32-415
Atlanta, GA 30303-3167
(404) 657-5700

IRB Study

PROJECT STATUS FORM

Title of Research:

_____

_____

_____

_____

Board Review Date:_____ Disposition _____

Board Review Date:_____ Disposition _____

Approval From:_____ To:_____

Request for continuing approval Mailed: _____ Received: _____

Board Review Date:_____ Disposition _____

Board Review Date:_____ Disposition _____

Approval From:_____ To:_____

Request for continuing approval Mailed: _____ Received: _____

Board Review Date:_____ Disposition _____

Board Review Date:_____ Disposition _____

Approval From:_____ To:_____

Communication from Investigator:
Type: _____
Date:_____
Type: _____
Date:_____
Type: _____
Date:_____
Type: _____
Date:_____
Other Information:

_____

Project Completion Date:_____
IRB Closed Date: _____

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GUIDANCE TO RESEARCHERS USING HUMAN SUBJECTS

MANUAL

Index

1. Introduction

The Department of Human Resources maintains an Institutional Review Board which is charged with assuring that the rights of human subjects of research conducted or sponsored by the Department are protected as outlined in federal and state policies and regulations. The Board is guided by the ethical principles set forth in the publication: "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research."
All research projects that involve human subjects must be submitted to the Board and approved by the Board prior to their initiation. These and other requirements for continuing contacts between the investigators and the Board are enumerated in this manual. The Board has the authority to suspend or terminate approval for research projects when certain requirements are

not met. Approval of research projects is based on the determination that all aspects of the project are in accordance with the procedures that are outlined in this manual and other applicable regulations and considerations.

Insuring the rights of human subjects of research is a collaborative effort of all those persons who are involved with the research project. The procedures that are outlined in this manual constitute the minimum framework to assure that subjects' rights are protected. It is the Board's responsibility to assess whether or not these minimum standards are met based on what is submitted to them. It is in the conduct of the research project, however, that the standards are implemented. The process of protecting subjects' rights, then, hinges on the performance of the investigators as they carry out the project.

It is hoped that the intent of these procedures will be helpful as a guide to investigators as they make the innumerable decisions necessary to conduct a research project. If there are questions, the Board may be reached at:

Georgia Department of Human Resources

Institutional Review Board
2 Peachtree Street, NW, Suite 32-415
Atlanta, Georgia 30303-3167
(404) 657-5700

2. Application Process

2.1. Who should apply for approval

Approval must be obtained for all research involving human subjects that is conducted by or sponsored by the Department. These terms are defined within the policy statement. Approval must be obtained prior to any involvement of the subjects. The approval by the Board is limited to a 12-month period and must be renewed annually to continue the involvement of subjects. Researchers must have no involvement with subjects unless they have current approval from the Board.

2.2. Application Procedures

Applications for approval are filed with the Executive Secretary of the Board in the Office of Regulatory Services. Applications are submitted using the attached two forms: "Application for Approval of Research Using Human Subjects," and "Format Guide for Consent Form." Applicants are to follow the instructions listed on the forms. Note that the information that appears in bold print should be replicated by the applicant on both the application form and the consent form. Note that the information that is italicized is to be substituted by the applicant with information that applies to the research project under consideration. The grant application or other description of the project may be submitted, but the required information must be submitted on the forms as indicated. No application will be considered until all the information is received by the Board. A complete application package includes: 1) a completed and signed "Application for Approval of Research Using Human Subjects;" 2) the proposed consent form; 3) any questionnaires or other written instructions to be given to subjects; and 4) an investigator's brochure, if the study is conducted under the Investigational New Drug regulations.

Note that the application should be submitted at least six weeks prior to the desired start time. Note also that no activity may begin until approval from the Board is received.

3. Informed Consent

Except as provided elsewhere in this directive, no investigator may involve a human subject in a research project unless the investigator has obtained the legally effective informed consent of the subject or the subject's guardian. An investigator shall seek such consent only under circumstances that provide the prospective subject or the guardian sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject and/or the guardian shall be in language that is understandable to the subject or guardian. No informed consent shall contain any language that waives or appears to waive any of the subject's legal rights or appears to release the investigator, the sponsor, or the institution or its agents from liability for negligence.

3.1. Elements of Informed Consent

The minimum elements of informed consent are found on the form that is attached to this procedure: "Format Guide for Consent Form." When appropriate, one or more of the following elements of information shall also be provided to each subject as part of the consent form:

a. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
c. any additional costs to the subject that may result from participation in the research;
d. all appropriate alternatives to participation, including nonparticipation;
e. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
f. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
g. the approximate number of subjects involved in the study;
h. if the design includes treatment and control groups (and/or placebo control groups), statements that describe how the subject will be assigned to groups; and,
i. for certain subjects, including patients in any institution of the Division of Mental Health, Mental Retardation, and Substance Abuse, a statement from the subject's attending physician that the subject understands the informed consent and is competent to give consent for participation in the study.
j.

3.2. Situations When Written Consent Not Required

The Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the Board finds and documents that the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: public benefit of service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs; and, the research could not practicably be carried out without the waiver or alteration. Projects that are conducted under this waiver must meet the provisions of O.C.G.A. §15-18-101 and related DHR Directives. In order for this waiver to be considered, the investigator must submit, along with the other requirements for application, the agreement concerning confidentiality of records and the statement from the appropriate official that the proposed project meets the requirements of O.C.G.A. §15-18-101 and other DHR Directives.
The Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the Board finds and documents that:

1. The research involves no more than minimum risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The consent cannot practicably be obtained and the research could not practicably be carried out without the waiver or alteration; and,
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The Board may waive the requirement for a signed consent form (but not the requirement for informed consent) in situations where the only record linking the subject and the research would be the signed consent document or in situations, such as phone interviews, where a signature is not feasible. An example would be an anonymous mailed questionnaire. In this situation, a cover letter could contain the elements of informed consent and a signature of the subject would not be required.
There are certain other "emergency" situations, detailed in 21 CFR , 50.23 &.24, where an intervention may occur without prior informed consent.

4. Approval Process

Application approval or disapproval will be communicated to the investigator and sponsor in writing. If the Board decides to disapprove an application, it will include in its written notification a statement of the reasons for its decision and will give the investigator an opportunity to respond in person or in writing. Should an application be disapproved, no further processing of the application will take place until the Board's concerns are met and a positive vote is obtained.

4.1. Types of Review and Criteria

The Board may follow one of three procedures for review of an application, depending on the characteristics of the project. The types of review and the criteria for each type are listed below.

4.1.1. Approval Without Detailed Review

Applications for projects in which the only involvement of human subjects is in categories that are described below may be approved by the Chairperson without further review. The categories are:

a. research conducted in established or commonly accepted education settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;
b. research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless 1) the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and 2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
c. research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under subparagraph 2. above, if 1) the human subjects are elected or appointed public officials or candidates for public office or 2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter;
d. research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available

or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects;

e. research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: 1) public benefit or service programs, 2) procedures for obtaining benefits or services under those programs, 3) possible changes in or alternatives to those programs or procedures, or 4) possible changes in methods or levels of payment for benefits or services under those programs; (For projects in this category, the investigator must submit, along with the other requirements for application, the agreement concerning confidentiality of records and the statement from the appropriate official that the proposed project meets the requirements of and other DHR Directives.)
f. taste and food quality evaluation and consumer acceptance studies if: 1) wholesome foods without additives are consumed, or 2) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

4.1.2. Expedited Review

For applications for projects meeting the below described eligibility requirements for expedited review, the review may be performed by the chairperson or by one or more Board members, designated by the Chairperson, who are experienced reviewers. In reviewing the research, the reviewers may exercise all the authorities of the Board except the reviewers may not disapprove the research. The reviewers may approve the application, or they may require modifications and grant approval once these modifications have been made. If they do not approve the application, it will be forwarded to the Board for a full Board review.

The eligibility requirements for expedited review are as follows: the application represents minor changes in a currently approved project, or the research is found to involve no more that minimum risk to the subject and appears on the list below: (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

a. collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction;
b. collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;
c. recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice (This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's

privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography,
thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible

range [for example, x-rays, microwaves]);

d. collection of blood samples by venipuncture in amounts not exceeding 450 milliliters in an eight week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant;
e. collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
f. voice recordings if made for research purposes such as investigations of speech defects;
g. moderate exercise by healthy volunteers;
h. the study of existing data, documents, records, pathological specimens, or diagnostic specimens;
i. research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the project will not involve stress to subjects;
j. research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

4.1.3. Full Board Review

Full Board review is required for all eligible projects that do not meet the criteria for either of the two above categories of review.

4.2. Review Criteria

In order to approve a research project, the Review Board will determine if all of the following are met:

a. risks to subjects are reasonable in relation to any anticipated benefits to subjects and the importance of the knowledge to be gained;
b. risks to subjects are minimized by using procedures that are consistent with sound research design, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
c. selection of subjects is equitable;
d. appropriate measures are in place to obtain and document the prior informed consent of the subjects or the subjects' guardians;
e. there are adequate provisions for protecting the confidentiality of data which identify individual subjects; and
f. there are adequate provisions for monitoring the collected data to ensure the safety of subjects and to protect their privacy by maintaining anonymity or confidentiality of the data.

For research projects that involve the participation of vulnerable subjects, there are specific requirements contained in the federal regulations. Compliance with these regulations will be assessed by the Board when a project involves any of these groups of subjects. The types of subjects and the associated federal regulation(s) are listed below.

Fetuses, pregnant women, and human in vitro fertilization - 45 CFR 46.201-46.211

Prisoners - 45 CFR 46.301-46.306

Children - 45 CFR 46.401-46.409

4.3. Continuing Review

Approval to conduct a project may be granted for a period of no more than one year. If the project is not completed by the end of the approved period, the investigator must apply for a continuation of the approval. The length of the approval period and the extent of continued review will be determined by the Board at the time of approval and will be communicated to the investigator. The Board will contact the investigator prior to the end of the approved period to solicit the required information in order to review the project for continued approval. The information requested on the "Continuing Review Form" is compiled at this time by the investigator and submitted to the Board. The Board considers the request and notifies the investigator of the decision.

4.3.1. Frequency and Extent Considerations

The length of time of approval for each project will be based on a consideration of the vulnerability of the subject population and the extent of risks to subjects. Special attention will be given to projects involving new procedures or treatments and projects involving placebo control groups. The following is a frequency guideline for approval periods:

a. New drug trials - 6 month approval period;
b. Projects involving pregnant women, children, or other vulnerable populations - 9 to 12 month review period; and
c. Projects involving minimal risks to subjects - 12 month approval period.

The extent of the continued review will be determined by an assessment of the vulnerability of the subject population, the extent of risks to the subjects, and a consideration of other factors of the research administration

and design. For example, for projects for which the investigator is not a DHR employee, the Board may require the DHR sponsor to perform an on-site visit of the project to determine compliance with the procedures stated in this manual. Another example is that for projects for whom the sponsor and the investigator are the same person, an uninvolved person may be asked to perform an on-site monitoring of the project.

4.3.2. Suspense or Termination of Projects

The Review Board may suspend or terminate approval of research that is not being conducted in accordance with requirements for the protection of human subjects and any research associated with unexpected serious harm to subjects. Any suspension or termination of approval will include a statement of the reasons for the Board's action and will be reported promptly to the investigator, to the Division or Office of the Department of Human Resources, and, if appropriate, to the U. S. Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), and other organizations.

If it is determined after the fact that any of these procedures were not followed in the course of the research project, then written notification of such findings will be sent to the investigator and all appropriate organizations, including the institution with which the investigator is affiliated.

The continuation of a research project after the expiration of the Board's approval is a violation of federal regulations. If the Board's approval has expired, research activities must stop. No new subjects may be enrolled in the project. If the investigator is actively pursuing renewal of approval with the Board and the Board believes that there are no overriding safety or ethical concerns, then the Board may exercise flexibility in allowing the project to continue for a brief time needed to complete the review process.

When study approval is terminated by the Board, in addition to stopping all research activities, any subjects currently participating should be notified that the study has been terminated. Procedures for withdrawal of enrolled subjects should consider the rights and welfare of the subjects. If follow-up of subjects for safety reasons is permitted/required by the Board, the subjects should be so informed and any adverse events or outcomes should be reported to the Board.

5. Responsibilities of Investigators

It is the responsibility of the investigator to design the project in such a way that minimizes risks to subjects and to continuously monitor the activities of the project to assure that the risks remain at a minimum. It is the responsibility of the investigator to report in writing the following information to the Board:

a. any reports requested by the Board, including continuing review information;
b. any changes in the project's protocol, including a change of DHR Sponsor; and
c. adverse events associated with the project.

Any proposed changes in previously approved projects must be approved by the Board and cannot become effective prior to being approved. Consideration of changes will be accomplished in the manner described for initial approval of applications.

In addition to reporting to the Board, the investigator must report adverse events as required to the Food and Drug Administration and must indicate to the Board such notification. The Board will acknowledge these reports in writing and will indicate one of the following: 1) the Board will review the report at the next meeting and the project may continue until a formal Board action is taken; or 2) the project must be discontinued immediately. The chairperson of the Board has the authority to make the decision concerning which course of action will be followed.

6. Appeals

A decision to disapprove a research project may be appealed by submitting a written request for reconsideration by the Review Board, including any additional data pertinent to the decision. Upon receipt, the request and any related documents will be conveyed to the Board for reconsideration. The reconsideration will be accomplished in the manner described for initial review. A negative decision by the Board cannot be reversed except by a vote of Board members.

DHR Institutional Review Board
2 Peachtree Street, NW, Suite 32-415
Atlanta, GA 30303-3167
(404) 657-5700

APPLICATION FOR APPROVAL OF RESEARCH USING HUMAN SUBJECTS

Title of Research Project:

Principal Investigator	*** DHR Sponsor**
Name:	Name:
Position:	Position:
Affiliation	Affiliation:
Address:	Address:
Telephone Number:	Telephone Number:
**Signature:	*Signature:

*Required if the principal investigator is not a DHR employee.
**Your signature indicates that you have read the DHR's "Guidance to Researchers Using Human Subjects Manual," and that you understand and agree to follow the procedures specified in the Manual. Your signature further attests that you assume responsibility for assuring that all aspects of and personnel involved with this project follow the specified procedures.
Date you would like approval for project to begin: _____
(Should be at least 6 weeks from date of submission to IRB)
Date you anticipate last contact with subjects:

_____

Date you anticipate completion of project: _____

IV. PLEASE COMPLETE THE APPLICATION AND FORWARD THIRTEEN COPIES OF THE APPLICATION AND ATTACHMENTS TO THE DHR INSTITUTIONAL REVIEW BOARD

DHR Institutional Review Board
2 Peachtree Street, NW, Suite 32-415
Atlanta, GA 30303-3167
(404) 657-5700

APPLICATION FOR APPROVAL OF RESEARCH USING HUMAN SUBJECTS

Respond to all ten statements listed below. Type each statement (in bold) and add your response for each number. If a statement does not apply, write "not applicable." Applications should not be over five pages. Do not send "method sections" or grant proposals. Do not respond to any statement with "see attachments."

1. Research Abstract
   State rationale and research question or hypothesis. Clearly explain why you are conducting this research, what are the anticipated benefits, and what is the importance of the knowledge to be gained.
2. Design
   Identify your research design and specific factors or variables, conditions, or groups in your study and any control conditions. Indicate the number of subjects assigned to each group, how they will be assigned to groups, and describe plans for data analysis.
3. Research Subjects
   a.Number and description of subjects
   Describe subject characteristics (age, gender, diagnosis, etc.).
   b.Method of selection/recruitment of subjects **Attach copies of any fliers, advertisements, etc. that will be used.**
   c.Compensation
   Describe any incentives or compensation offered for participation.
4. Procedures Summary
   State in chronological order what the subjects are expected to do, or describe what procedures the subjects will be involved with. If deception is necessary, justify and describe. Submit debriefing procedures that include an explanation to subjects about how and why they were deceived, as well as providing an educational summary.
5. Materials
   List, in sequence, all questionnaires and/or tasks to be given to subjects. Attach a labeled copy of all written instruments to each copy of this application. Attach copies of the investigatorəs brochure, if the study is conducted under the Investigational New Drug regulations.
6. Confidentiality Assurances
   If the results of participation are not public or anonymous, then describe how confidentiality of information will be maintained. Describe how long information, data, or other items will be kept. Describe destruction techniques. If data, information, or other items are to be kept indefinitely, so state, and give purpose of retention and method to assure continued confidentiality.
7. Risks Summary
   a. **Current Risks** Describe any psychological, social, legal, economic, or physical discomfort, stress, or harm that might occur to subjects as a result of their participation in this research. Describe how these risks will be held to the absolute minimum.
   b. **Future Risks** Describe any future risks that subjects may experience as a result of their participation in this research. Describe how these risks will be kept at an absolute minimum.
8. Benefits
   a.To Subjects
   Describe any potential beneficial effects that participation in this research might have for subjects.
   b. To Humankind
   Identify any potential benefits that humankind in general will gain from this research.

9. Vulnerable Subjects
   If vulnerable subjects (including minors) are involved, outline procedures that will be used to obtain their agreement to participate (in addition to informed consent from parents or guardians). Describe any other procedures that will used to safeguard the rights of vulnerable subjects.
10. Informed Consent
    Describe the procedure that will be used to obtain legally effective informed consent from subjects. Attach copies of the form to be used.

Georgia Department of Human Resources Institutional Review Board

FORMAT GUIDE FOR CONSENT FORM

(This guide contains the minimum elements that are necessary for approval of research using human subjects . Additional information may be required in some circumstances. Refer to the "Guidance to Researchers Using Human Subjects Manual" for more information. The language in the form should be understandable to the subjects and be stated in the first person.)

I agree to participate in the research titled (*title of research)* which is being conducted by (*investigator's name, title, affiliation, phone number*). I understand that my participation is entirely voluntary. I understand that I can withdraw my consent at any time (without penalty *OR describe penalty)* and can have the results of my participation, to the extent that it can be identified as mine, returned to me, removed from the record, or destroyed.

The following points have been explained to me:

1. The reason for the research is (*give a short justification)*.
2. The benefits that I may expect for the research are (*list specific benefits to the subject)*.
3. **The procedures are** (Describe what will happen to the subject, including the time, place, and duration. Describe any questionnaires that are used. In studies involving experimental treatments, identify the parts that are new or experimental, and indicate how they differ from other procedures that could be followed. If deception is necessary, state: **"In order to make this study a valid one, some information about my participation will be withheld until after the study."**)
4. The discomforts or stresses that I may face during this research are *(List discomforts or stresses or, if none are foreseen, then include this statement:* "No discomforts or stresses are foreseen."*)*
5. **Participation involves the following risks** (List all potential physical, psychological, social, or legal risks. Also list the steps to be taken if harm should come to the subject, including any availability of medical treatment or referrals if needed. If no risks are foreseen, then include this statement: **"No risks are foreseen."**)
   - The results of my participation will not be confidential, but *(describe any controls on access to data)*. *(OR)*
   - The results of my participation will be anonymous. *(OR)*
   - The results of my participation will be confidential, and will not be released in any individually identifiable form without my prior written consent, unless otherwise required by law. *(Describe any special procedures regarding anonymity or confidentially. For example, describe how data will be stored, how identifiers will be removed, give erase dates for tapes, give date data will be destroyed, etc. If data, tapes, or other items are to be kept indefinitely, so state, with purpose for retention, and method to assure confidentiality.*)
7. The investigator will answer any questions I have about the research, now or during the course of the study.
8. I may contact *(Investigator's IRB - name of contact person, phone number and address)*, who is not directly involved with this research, if I have any questions about my rights as a subject in this study.

(Under some circumstances the following assurance is necessary: I have examined *(name of subject)* and found him/her to be competent to give informed consent for participation in this study.

Printed Name of Physician_____

Signature_____**Date**_____

_____ _____
Signature of Investigator **Date**

_____ _____
Signature of Subject **Date**

PLEASE SIGN BOTH COPIES OF THIS FORM. KEEP ONE COPY AND RETURN THE OTHER TO THE INVESTIGATOR.

GEORGIA OPEN MEETINGS ACT AND GEORGIA OPEN RECORDS ACT

I Legal References

O.C.G.A. § 50-14-1, et seq. and O.C.G.A. § 50-18-70, et seq.
The Open Records and Open Meetings Acts are often referred to as Georgia's "Sunshine Laws." Recent legislation adopted by the Georgia General Assembly has expanded significantly the laws governing the conduct of meetings by governmental and certain private entities and streamlined the public's access to records maintained by these entities. It is incumbent on all those conducting business on behalf of the state to recognize the significance of these laws, and to see that they are complied with strictly and fully.

II Open Meetings

The Open Meetings Act applies to the governing body of an "agency" or its committees in the conduct of its business. The law allows citizens an opportunity to monitor local officials and certain private concerns under contract for state funded services to insure fairness and openness in the conduct of its affairs. An "agency", according to the statute, can take many forms and typically includes all state department's, agencies, boards and commissions, and authorities and those entities' counterparts at the county, municipal and local level. Of particular significance is the recent adoption of legislation that includes certain nonprofit organizations among those that now must comply with the Open Meetings Act. However, the nonprofit organization must receive a direct allocation of tax funds from a governing authority in excess of 33 α of its total allocation in order for the requirements of the Act to apply.

A. Meetings Covered by Act

According to O.C.G.A. § 50-14-1(a)(2), a meeting that must be open is one in which there is a gathering of a quorum of members of an agency at a designated time and place, pursuant to notice, during which any public matter, official business or policy is discussed or presented. This applies equally to any standing or special committees within the organization as well. If there is not a quorum of either the agency or a committee, then the law does not apply. There are also several exceptions to the Act:

1. The Act authorizes "an agency with statewide jurisdiction" to conduct business meetings via teleconference, but this would not be applicable to most agencies under the act.

2. The gathering of a quorum of a board or committee to inspect a facility within its jurisdiction.

3. Meeting with the board or committee of another agency as long as conducted outside the agencies' jurisdiction and where no final action is taken.

4. Meetings of the medical or administrative staff, advisory committees that may not act on behalf of the board, social gatherings where business is not discussed or action taken.

B. Matters Excluded from the Act

1. Staff meetings held for investigative purposes as required by law

2. Real estate acquisitions
3. Staff privileges or abortions
4. Personnel matters
5. Commercially valuable plans, proposals
6. Peer review
7. Attorney – Client privilege

Because of the legislative intent that the business of the various agencies be open to all, and with few exceptions, meetings closed to the public must be done in strict compliance with the law. If in doubt as to the legality of closing a meeting, legal counsel should be consulted.

C. Procedural Requirements

1. **Notice** – Time, place and dates of meetings must be made known to the public at least 24 hours in advance. Generally, the posting of the time and date at the place where meetings are regularly held is sufficient. However, where meeting locales move about, other means, such as placing a notice in the areas' legal organ, may be required. The statute covers most contingencies regarding notice and should be consulted if in doubt.

2. **Agenda** – Any time within two weeks of the scheduled meeting, an agenda must be made available to the public outlining all matters expected to come up at the meeting. The agenda shall be posted at the meeting sight and made available upon request by third parties. An item not listed on the agenda, however, may still be considered and acted upon.

3. **Records** – After an open meeting has concluded, a summary of the matters acted upon and the members present must be prepared and made available for public inspection within two business days of the meeting. Minutes of the meeting, however, must eventually be prepared and ready for distribution no later than immediately following the next regular meeting of the board or committee. These minutes must contain, at a minimum, names of the members present, a description of every motion or proposal made and a record of all votes. Minutes of closed or "executive sessions" need not be kept as long proper procedures have been followed.

4. **Closed meetings** – Whenever a meeting is closed to the public, the proper procedure must be carefully followed. A motion to close the meeting must be made, members must vote, and the reasons for the closure stated and recorded. The record used to memorialize a closed meeting is an affidavit, filed by the presiding officer, and stating that provision of the law which allows for the session to be closed to the public. Minutes of the closed session may or may not be maintained but if so, filed separately from the public portion and need not be distributed publicly.

D. Penalties

Any official action taken during a meeting not in compliance with this statute is not binding. Any such challenge to the conduct of a meeting and the resulting action taken must be

commenced within 90 days of the contested action. Any person who knowingly and willfully participates in a meeting in violation of the Open Meetings Act is guilty of a misdemeanor and may fined in an amount up to $500.00. However, any person that knowingly and willfully files a false affidavit pursuant to the closed meeting procedure, is guilty of false swearing, and may be fined up to $1,000 or imprisonment from 1 to 5 years.

III Open Records

O.C.G.A .§50-18-70 (a) defines "public records" as all documents, papers, letters, maps, books, tapes, photographs computer based or generated information, etc., maintained or received in the course of business of a public office or agency. More recently, "public records" also include records maintained by a private person or entity on behalf of a public office or agency. The definition of "agency" is the same as in the Open Meetings section; thus private entities whose tax dollar allocation is at least 33 α of their total allocation are subject to the Open Records Act.

A. Right to Access and to Make Copies

All public records, except those excluded by law, must be open for personal inspection and copying by any citizen at a reasonable time and place. The person making the request does not have to demonstrate a personal or special interest in the record(s) requested.

1. **Responding to requests** – Typically, a request for records goes to the agencies' custodian of records or an agency designee. Upon receipt of a request, it must first be determined if the records requested are accessible under the act. If so, the record must be available for inspection and copying by the requestor within three business days of the request. If the information requested comes within the ambit of the Act, but is not available within the three days, the agency must notify the requestor of the documents unavailability and provide a timetable for eventual inspection and copying.
2. **Costs** - The costs for copying may not exceed .25 per page. DHR's current copy charge is .10 per page. Also, an agency may charge for retrieval and other administrative costs. An hourly charge for administrative costs may not exceed the salary of the lowest paid full-time employee capable of performing the task. Information maintained by computer is accessible.

B. When public disclosure not required (O.C.G.A. § 50-18-72)

Public disclosure shall not be required for the following records

1. Records specifically required by the federal government to be kept confidential.
2. Medical or veterinary records and similar files.
3. Records prepared for law enforcement purposes to the extent such records may contain confidential identifying information, the disclosure of which may jeopardize the safety of an individual or investigation.
4. Records of law enforcement, prosecution or other regulatory agencies compiled in the course of an investigation.
   4.1) Individual Georgia Uniform Motor Vehicle Reports (numerous exceptions).
5. Records of a confidential nature regarding a public official appointment or hiring or investigative information regarding same.
6. Real estate appraisals made for a state or local agency.
7. Records that would reveal the identity of one under consideration for appointment to an agency head (information may be released under certain conditions).
8. Certain records related to staff services of members of the General Assembly.

9. Records donated for historical purposes where the owner places restrictions to access.

10. Records maintained by the Department of Natural Resources (DNR) designating certain locations to be of historic value (to avoid possible harm to the property).
11. Records maintained by DNR identifying rare plants, animals, etc. to avoid possible harm or destruction.
    11.1) An individual's social security number and insurance or medical information in personnel records may be redacted from such records.
12. Public records that would disclose an "electronic signature".
13. Records that would reveal the home address phone number, social security number or medical information of, among others, law enforcement employees, judges, correctional employees and prosecutors.

Furthermore, the Open Records Act shall not apply to trade secrets, proprietary information, Attorney-Client privilege, confidential tax matters, computer software and programs, personnel records (narrowly construed, see 11.1 above) and records relating to pending administrative proceedings. This list of exceptions and non-applicability of the Act to certain records cannot substitute for a through reading of the Act itself and consultation with legal counsel when in doubt about the Act's applicability to a request for documents.

C. Penalty (O.C.G.A. § 50-18-74 (a))

Any person knowingly and willfully violating the provisions of this article by failing or refusing to provide access to records not subject to exemption…or failing to provide access to such records within the time limits set forth…shall be guilty of a **misdemeanor** and upon conviction shall be punished by a fine not to exceed $100.00.

CONSUMER PERSONAL NEEDS SPENDING ACCOUNTS

Individuals served in residential services shall contribute to the cost of room and board expenses based on the amount of their benefits (SSI or SSDI, Veteran's and Railroad Retirement benefits) less an amount for Personal Spending Needs as specified by the Division (for FY'06 the Personal Spending Needs amount is $65 per month). If the benefit exceeds the amount of the room and board costs, benefits may be used for other consumer personal expenses. In most cases, Contractors become the payee of residential consumers' checks and maintain consumers' personal needs funds. The Contractor shall keep all records pertaining to personal needs accounts (including bank statements and bank books) and at least one set of such records shall be maintained at the consumer's place of residence.

Residents have the right to manage their own funds. Consumers' ability to manage their funds shall be documented in their respective individual services plan. In instances where a residential services consumer or his/her representative continues as payee and manages his/her own funds, the consumer or his/her representative is responsible for forwarding benefit funds less the established Personal Spending amount to the Contractor.

MANAGEMENT AND PROTECTION OF CONSUMER FUNDS

In the event the provider organization has to assume responsibility for the safeguarding or management of any consumer valuables or finances, pursuant to PPr. 4.(pg. III-B-2) of this Manual, the following requirements are considered minimal and must be fulfilled by the provider organization:

I. The organization must have written and implemented policies and procedures for safeguarding consumer possessions, valuables and finances. All policies and procedures shall be in compliance with the guidelines of the Social Security Administration and any other laws or regulations of the federal and state governments. Such policies and procedures must be filed with the Regional Office upon execution of the contract or prior to the organization undertaking the management of any consumer valuables or finances.

II. The written and implemented policies must provide for the following:

A. A strict prohibition, punishable by termination, for any employee, agent or representative of the organization to be listed or designated, either directly or indirectly, as a beneficiary, payee or other recipient of any funds of the consumer, including but not limited to, any insurance, burial or trust benefits;

B. A procedure in accordance with the guidelines listed below to ensure the timely deposit and accounting of all consumer funds (e.g., trusts, work-related income, Social Security, disability benefits, gifts, etc.) in an account in the individual name of each consumer receiving any such funds;

1. Funds may not be pooled or co-mingled in any organizational account or other combined account without the express written consent of the consumer, the family and each payer of said funds.
2. Funds not needed for ordinary use by the consumer on a daily basis shall be deposited in an account insured by agencies of or corporations chartered by the state or federal government and in a form, which clearly indicates that the organization has only a fiduciary interest in the funds.
3. Funds received from a resident or on his/her behalf may be deposited in an interesting-bearing account; provided, however, that any interest earned on such account shall accrue to the consumer.
4. To the extent that certain funds are properly due the organization for services, goods or donations, said funds must first be deposited to the individual consumer account and then subsequently disbursed in accordance with these requirements and the written policies of the organization.

C. A requirement that consumer funds may only be disbursed upon request or authorization of the consumer and/or his/her family, if appropriate, and, in the case where the organization serves as the designee to receive and disburse funds on behalf of the consumer, upon signature or written authorization of two independent staff members or organizational representatives.

D. A procedure or set of procedures to assure that at least two people, other than those having authorization to receive and disburse funds on behalf of any consumer, independently reconcile consumer bank and/or account records on a monthly basis.

E. A procedure for establishing and maintaining a written record of all financial arrangements and transactions involving the resident's funds. Such record shall be made available to the resident, his/her family or guardian, the Regional Office, and any other legally authorized representative for inspection and copying upon request.

F. A method for providing to each consumer on at least a quarterly basis a written statement showing the current balance of any account(s) and an itemized listing of all transactions occurring during that quarter; and

G. A procedure or set of procedures to account for and inventory consumer possessions to include insurance and other benefits policies (exclusive of consumer funds) on a semi-annual basis to assure clothing, personal effects, memorabilia, and other items of personal value are protected and, as appropriate, remain in the consumers possession during the course of his/her time receiving care and/or services from the organization.

III. Any organization which has assumed responsibility for safeguarding and/or managing consumer possessions or finances shall submit to the Regional Office on a quarterly basis a statement of compliance with the requirements stipulated herein. Such statement of compliance shall indicate that all policy and procedural requirements have been followed, that all funds are properly accounted for and reconciled, and shall be signed by the chief executive officer of the organization and, if applicable, the chair of the governing board.

IV. In the case of any breach of these procedures or any loss, theft or misappropriation of consumer possessions or funds, the organization shall immediately notify the Regional Office and shall document the occurrence(s) and any redress which has occurred. The provider organization bears full liability to replace, either through insurance, bond, surety or cash, any funds illegally or inappropriately taken from a consumer by any employee, agent or representative of the organization.

Georgia Department of Human Resources **Division of Mental Health, Developmental Disabilities and Addictive Diseases**	POLICY NO: 2.101
Applicability: • State Hospitals • Public and Private community providers • OTP & State-operated community programs • State MHDDAD office • Regional MHDDAD offices	REFERENCE: Official Code of Georgia 37-1-2; 37-1-20; 37-2-1 et seq.; 37-3-166; 37-3-2; 37-4-125; 37-4-3; 37-7-166; 37-7-2; 30-5-1 et seq.; 19-7-5; 16-6-5.1; DHR Rules and Regulations for Patients' Rights, Chapters 290-4-6; DHR Rules and Regulations for Clients' Rights 290-4-9.
SUBJECT: Reporting of Consumer Deaths and Critical Incidents	**Effective date: July 1, 2005** **Scheduled Review Date: May 23, 2006**
Attachments: A-Critical Incident Definitions B-Critical Incident Report C-Reporting to other Agencies	**APPROVED:** **- signed -** **Gwendolyn B. Skinner, Director MHDDAD**

I. POLICY

It is the policy of the Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD) to maintain a safe and humane environment for consumers, and to prevent abuse, neglect and exploitation of consumers. The DMHDDAD uses a standardized process for reporting deaths and critical incidents that involve consumers being served by the DMHDDAD in state hospitals and community providers.

II. DEFINITIONS

Category I Incidents: Unexplained or suspicious deaths (including suicides), allegations of physical abuse, allegations of neglect, allegations of sexual assault/exploitation, medication errors with adverse consequences, consumer to consumer assault resulting in injury requiring treatment beyond first aid, seclusion/restraint resulting in injury requiring treatment beyond first aid (See Attachment A).

Category II Incidents: Deaths (other than unexplained or suspicious), allegations of verbal abuse, allegation of financial exploitation, consumer who leaves the grounds of a state hospital without permission, consumer who is unexpectedly absent from a community residential program, medical hospitalization of a consumer of a state hospital or community residential program, consumer injury requiring treatment beyond first aid, seclusion or restraint resulting in injury requiring minor first aid, consumer-to-consumer assaults or incidents with injury requiring minor first aid, vehicular accidents with injury while consumer is in a state vehicle or is being transported by community or hospital staff, incident occurring at a providers site which required intervention of law enforcement services, criminal conduct by consumer (See Attachment A).

Community Provider: Any person or entity providing community-based disability services through a contract with or authorized by the DMHDDAD and/or providing Medicaid services authorized by DMHDDAD. "Community Provider" includes any state owned or operated community program. For purposes of this policy, community provider includes services provided through a subcontractor. "Community Provider" does not include state hospital inpatient care units, nor does it include private community providers who do not have a contract, Memorandum of Understanding, Letter of Agreement or service authorization with the state to provide DMHDDAD services.

Consumer: An individual enrolled with a community provider for disability services, seeking services or admission at a state hospital, or on the census of a state hospital. The terms "client" or "patient" are used interchangeably with consumer.

Critical Incident: Any event that involves an immediate threat to the care, health or safety of any consumer in community residential services, on site with a community provider or hospital, in the company of a staff member of a community provider or hospital, or absent without leave from inpatient or residential services. Critical incidents include, but are not limited to, all deaths as defined and all incidents as listed in categories I and II.

Critical Incident Database: DMHDDAD web-based system for entering data about critical incidences.

Deaths: The death of any consumer in a community residential service, on the census of a state hospital, on site with a community provider or hospital, in the company of staff of a community provider or hospital, or absent without leave from inpatient or residential services. Deaths include suicides and the death of a consumer occurring within two (2) weeks following the consumer's discharge from a state hospital or community residential provider AND the death of any consumer transferred or discharged to a medical facility for treatment of any illness or injury that occurred during hospital or community provider supervision, regardless of the time that has elapsed since the transfer or discharge.

Disability Services: Direct services to an individual, or services, which are designed to prevent or ameliorate the effect of a disability.

Exploitation: The illegal or improper use of an individual's labor, property or resources for another's profit or advantage and/or the failure to accurately account for the consumer's funds by a payee.

High-Visibility Incident: Critical incidents as defined in this policy, which have system-wide impact, have impact upon, or relevance to, any ongoing litigation of DHR or DMHDDAD, or may have significant impact upon, or significant relevance to, issues of DHR or DMHDDAD public concern and/or are likely to be reported in the media.

Neglect: An act or omission by any individual or organization responsible for providing services that creates a significant risk of injury or death to a consumer.

Physical Abuse: The willful infliction of physical pain, physical injury, or unreasonable confinement. For purposes of this policy, "willful" means other than accidental.

Senior Executive Manager: The supervisor administratively in charge at the time of the incident.

Sexual Assault/Exploitation: Any sexual contact between an employee and a consumer. Includes the solicitation of a consumer by an employee for sexual purposes.

State Hospital: A state Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD) hospital facility.

Unexplained or Suspicious Death: A death not related to a known condition and that may have resulted from an act of omission or commission while receiving care from a DMHDDAD provider. This includes suicides.

Verbal Abuse: The use of words or gestures by an employee to threaten, coerce, intimidate, harass or humiliate a consumer.

III. PROCEDURES

A. Reporting deaths

1. Upon discovery of a death of a consumer, the state hospitals/community providers immediately take any actions necessary to protect other consumers' health, safety and rights. These actions may include:

   - Immediate and ongoing medical attention, as appropriate;
   - Suspension or reassignment of an employee from a position involving direct care pending the outcome of any investigation; and

- Other measures to protect the health, safety and rights of other consumers, as necessary.

2. Upon discovery of the death of a consumer, the state hospital/community provider:

   - Immediately calls local law enforcement and the coroner/medical examiner if law enforcement has not called the coroner/medical examiner;
   - Calls the guardian, if any, and/or next of kin of the deceased after authorization from the coroner/medical examiner;
   - In the case of a child's death in a state hospital, designates a staff person, who is qualified to provide crisis/grief counseling, to notify the parent/guardian in person of the death;
   - Notifies the support coordinator, if applicable, within 24 hours; and
   - In instances when DFACS, DJJ, or APS has custodial or commitment responsibility, notifies the worker within 24 hours.

3. The state hospital/community provider immediately reports by phone all unexplained or suspicious deaths to the Investigations Section. This call must be made as soon as possible, but at least within two (2) hours of the death. The provider should present any information available at the time of the telephone report that is required on the *Critical Incident Report* form (Attachment B). A copy of the *Critical Incident Report* form must be submitted on the same day as the consumer's death, or on the next business day if the death occurred after business hours or on a weekend or holiday. The senior executive manager is responsible for ensuring that both the telephone notification and the written *Critical Incident Report* are submitted as required. In the case of state hospitals, this is the responsibility of the Regional Hospital Administrator.

4. For all unexplained or suspicious deaths, the Investigations Section notifies the Director of MHDDAD, the Division Medical Director and the Regional Coordinator immediately.

5. When there is suspicion that a crime has been committed in a state hospital, the Investigations Section consults with the Division Director prior to contacting the Georgia Bureau of Investigation (GBI).

6. For all other consumer deaths, the state hospital/community provider transmits, by fax or electronically, the *Critical Incident Report* form (Attachment B) to the Investigations Section. The report must be submitted on the same day as the consumer's death or on the next business day if the death occurred after business hours or on a weekend or holiday.

7. The DMHDDAD Medical Director serves as consultant to the Investigations Section as needed.

8. The state hospital/community provider requests that the coroner/medical examiner conduct an autopsy and provides sufficient facts to the coroner/medical examiner regarding the death.

9. In the event that the coroner/medical examiner decides not to perform an autopsy, the state hospital/community provider ensures that the coroner/medical examiner's decision is documented, and if known, the rationale for the decision.

10. For consumer deaths that must be reported to other agencies or offices as required by law or regulation, the state hospital/community provider is responsible at all times for notifying such agencies and offices in a timely manner. (See Attachment C)

B. Reporting all other Category I and II Critical Incidents (excluding deaths)

1. Upon discovery of a Category I critical incident other than death, state hospitals/community providers immediately take any action necessary to protect consumers' health, safety and rights. These actions may include:

   - Contacting 911 or other emergency services as needed;
   - Immediate and ongoing medical attention, as appropriate;
   - Removal of an employee from direct contact when the employee is alleged to have been involved in abuse or neglect until such time as the state hospital/community provider has sufficiently determined that such removal is no longer necessary; and
   - Other measures to protect the health, safety and rights of the individual, as necessary.

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2. The state hospital/community provider immediately calls:

   - Local law enforcement and the Investigations Section if there is reasonable suspicion that a crime has been committed; and
   - The consumer's guardian and/or next of kin, as appropriate with respect to confidentiality regulations.

3. When there is suspicion that a crime has been committed in a state hospital, the Investigations Section consults with the Division Director prior to contacting the GBI.

4. The state hospital/community provider immediately reports all Category I critical incidents to the Regional Hospital Administrator/community provider administrator.

5. The state hospital/community provider immediately reports by phone all high visibility Category I and II critical incidents to the Investigations Section. This call must be made as soon as possible, but at least within two (2) hours of the high visibility incident. A *Critical Incident Report* form (Attachment B) must be submitted on the same day as the high visibility incident or on the next business day if the incident occurred after business hours or on a weekend or holiday.

6. For high visibility incidents, the Investigations Section notifies the Director of MHDDAD, the Regional Coordinator, and the Department of Human Resources (DHR) Office of Communications.

7. For all other Category I critical incidents, the state hospital/community provider transmits, by fax or electronically, the *Critical Incident Report* form (Attachment B) to the Investigations Section on the same day as the Category I incident, or on the next business day if the incident occurred after business hours or on a weekend or holiday.

8. For all other Category II critical incidents, The *Critical Incident Report* (Attachment B) is faxed or electronically sent to the Investigations Section within 24 hours of the incident or on the next business day if the incident occurred after business hours or on a weekend or holiday.

9. When a consumer has an assigned support coordinator, the state hospital/community provider reports the Category I or II critical incident by telephone to the support coordinator within 24 hours.

10. For Category I and II critical incidents that must be reported to other agencies or offices as required by law or regulation, the state hospital/community provider is responsible at all times for notifying such agencies and offices in a timely manner (See Attachment C).

C. Reports of Incidents by persons other than staff of state hospitals or community provider

1. Consumers, family members of consumers, support coordinators or any other persons may initiate reports of critical incidents as needed.

2. Upon discovery of incidents not already reported by the state hospital/community provider, support coordinators report the incidents in accordance with procedures outlined in section III., B.

3. When information about a critical incident is received by a state hospital/community from any person other than support coordinators, the staff receiving the information completes the *Critical Incident Report* form and follows procedures outlined in section III., B.

4. When information about a critical incident is received by the Investigations Section, the staff receiving the information completes the *Critical Incident Report* form.

D. Administrative Review of *Critical Incident Report* form

1. State hospitals/community providers perform an administrative review of all *Critical Incident Reports*. The administrative review includes, at a minimum:

- Reading the *Critical Incident Report*;
- Reading all statements and reports associated with the incident;
- Requiring and ensuring the completion of any incomplete or missing documentation; and
- Signing as the administrative reviewer on the *Critical Incident Report* form.

2. For state hospitals, the Regional Hospital Administrator or designated executive staff conducts the administrative review of all *Critical Incident Report* forms (Attachment B).

3. For community providers (including state-operated community programs), the provider defines in their internal policy the supervisory staff appropriate and available to perform the administrative review of all *Critical Incident Report* forms.

4. The Investigations Section reviews all *Critical Incident Reports* for completeness and contacts the state hospital/community provider for changes and additional information, as appropriate.

5. The Investigations Section in all cases obtains a copy of the death certificate from the Division of Public Health. This copy may not be reproduced or released outside the Division of MHDDAD.

E. Computer data entry

1. DMHDDAD maintains a consumer death and critical incident database to identify patterns and to perform trend analyses.

2. Each state hospital/community provider designates one or more persons to be responsible for entering critical incident and death information into the database. Entries must be made within two (2) business days of the event or knowledge of the event.

3. The Investigations Section enters critical incidents and death information received from the community providers into the database.

F. Investigations of Critical Incidents

1. The Investigations Section conducts investigations of all Category I critical incidents, in accordance with the Investigating Consumer Deaths and Critical Incidents policy, 2.201. If the Investigations Section determines that the provider should conduct the investigation, the provider is notified within three (3) hours of receipt of the initial report.

2. State hospitals and community providers conduct investigations of Category II critical incidents, in accordance with the Investigating Consumer Deaths and Critical Incidents policy, 2.201.

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G. Procedures for Data Analysis

1. The deaths and critical incidents reporting processes are monitored by the Investigations Section to include:

   - Entry of all Critical Incident Reports into the database;
   - Timeliness of Critical Incident Reports entered into the database; and
   - Patterns of critical incidents occurring in state hospitals/community providers.

2. State hospitals/community providers have procedures for analyzing incident patterns. Incidents include the following:

   - Incidents not required to be reported by this policy utilized for internal quality improvement programs; and
   - Incidents reported through this policy.

3. Information about incidents is utilized by the Division's Quality Improvement program to evaluate the quality of services.

Georgia Department of Human Resources **Division of Mental Health, Developmental Disabilities and Addictive Diseases**	POLICY NO: 2.201
Applicability: • State Hospitals • Public and Private community providers • OTP & State-operated community programs • State MHDDAD office • Regional MHDDAD offices	REFERENCE: Official Code of Georgia 37-1-2; 37-1-20; 37-2-1 et seq.; 37-3-166; 37-3-2; 37-4-125; 37-4-3; 37-7-166; 37-7-2; 30-5-1 et seq.; 19-7-5; 16-6-5.1; DHR Rules and Regulations for Patients' Rights, Chapters 290-4-6; DHR Rules and Regulations for Clients' Rights 290-4-9.
SUBJECT: Investigating Consumer Deaths and Critical Incidents	**Effective date: July 1, 2005** **Scheduled Review Date: May 23, 2006**
Attachments: A-Protocol for Investigations B-Final Investigative Report Format C-Review of Final Investigative Report form D-Request for Extension E-Corrective Action Plan	**APPROVED:** **- signed -** **Gwendolyn B. Skinner, Director MHDDAD**

I. POLICY

It is the policy of the Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD) to maintain a safe and humane environment for consumers, and to prevent abuse, neglect and exploitation of consumers. The DMHDDAD uses a standardized process for investigation of critical incidents and deaths that involve consumers being served by the DMHDDAD in state hospitals and community providers.

II. DEFINITIONS

Category I Incidents: Unexplained or suspicious deaths (including suicides), allegations of physical abuse, allegations of neglect, allegations of sexual assault/exploitation, medication errors with adverse consequences, consumer to consumer assault resulting in injury requiring treatment beyond first aid, seclusion/restraint resulting in injury requiring treatment beyond first aid.

Category II Incidents: Deaths (other than unexplained or suspicious), allegations of verbal abuse, allegation of financial exploitation, consumer who leaves the grounds of a state hospital without permission, consumer who is unexpectedly absent from a community residential program, medical hospitalization of a consumer of a state hospital or community residential program, consumer injury requiring treatment beyond first aid, seclusion or restraint resulting in injury requiring minor first aid, consumer-to-consumer assaults or incidents with injury requiring minor first aid, vehicular accidents with injury while consumer is in a state vehicle or is being transported by community or hospital staff, incident occurring at a providers site which required intervention of law enforcement services, criminal conduct by consumer.

Community Provider: Any person or entity providing community-based disability services through a contract with or authorized by the DMHDDAD and/or providing Medicaid services authorized by DMHDDAD. "Community Provider" includes any state owned or operated community program. For purposes of this policy, community provider includes services provided through a subcontractor. "Community Provider" does not include state hospital inpatient care units, nor does it include private community providers who do not have a contract, Memorandum of Understanding, Letter of Agreement or service authorization with the state to provide DMHDDAD services.

Consumer: An individual enrolled with a community provider for disability services, seeking services or admission at a state hospital, or on the census of a state hospital. The terms "client" or "patient" are used interchangeably with consumer.

Corrective Action Plan: A document which identifies and analyzes problems within the provider organization and prescribes corrective action steps which, when implemented, are likely to prevent the recurrence of similar problems and improve the quality of consumer care. A corrective action plan must identify the person(s) responsible for ensuring that action steps are completed and reviewed for efficacy and establishes a schedule for completion and follow-up of all action steps.

Critical Incident: Any event that involves an immediate threat to the care, health or safety of any consumer in community residential services, on site with a community provider or hospital, in the company of a staff member of a community provider or hospital, or absent without leave from inpatient or residential services. Critical incidents include, but are not limited to, all deaths as defined and all incidents as listed in categories I and II.

Critical Incident Database: DMHDDAD web-based system for entering data about deaths and critical incidences.

Deaths: The death of any consumer in a community residential service, on the census of a state hospital, on site with a community provider or hospital, in the company of staff of a community provider or hospital, or absent without leave from inpatient or residential services. Deaths include suicides and the death of a consumer occurring within two (2) weeks following the consumer's discharge from a state hospital or community residential provider AND the death of any consumer transferred or discharged to a medical facility for treatment of any illness or injury that occurred during hospital or community provider supervision, regardless of the time that has elapsed since the transfer or discharge.

Disability Services: Direct services to an individual, or services, which are designed to prevent or ameliorate the effect of a disability.

Exploitation: The illegal or improper use of an individual's labor, property or resources for another's profit or advantage and/or the failure to accurately account for the consumer's funds by a payee.

Final Investigative Report: A written summary of an investigation conducted by the Investigation Section, state hospitals or community providers of an alleged critical incident or death.

High-Visibility Incident: Critical incidents as defined in this policy, which have system-wide impact, have impact upon, or relevance to, any ongoing litigation of DHR or DMHDDAD, or may have significant impact upon, or significant relevance to, issues of DHR or DMHDDAD public concern and/or are likely to be reported in the media.

Investigator: A trained staff person who is designated to perform investigations into critical incidents.

Neglect: An act or omission by any individual or organization responsible for providing services that creates a significant risk of injury or death to a consumer.

Physical Abuse: The willful infliction of physical pain, physical injury, or unreasonable confinement. For purposes of this policy, "willful" means other than accidental.

Sexual Assault/Exploitation: Any sexual contact between an employee and a consumer. Includes the solicitation of a consumer by an employee for sexual purposes.

State Hospital: A state Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD) hospital facility.

Unexplained or Suspicious Death: A death not related to a known medical condition and that may have resulted from an act of omission or commission while receiving care from a DMHDDAD provider. This includes suicides.

Verbal Abuse: The use of words or gestures by an employee to threaten, coerce, intimidate, harass or humiliate a consumer.

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III. PROCEDURES

A. Investigation of unexplained or suspicious deaths

1. The Investigations Section conducts all investigations of unexplained and suspicious deaths.

2. The investigation includes:

- Interviewing consumers, staff and other involved parties;
- Reviewing all related documentation; and
- Collaborating with outside agencies, as applicable.

3. All investigations completed by the Investigations Section must be thorough and must address, at a minimum, those items identified in the *Protocol for Investigations* (Attachment A).

4. If, at any time during the investigation, evidence of criminal conduct is discovered, the Investigations Section immediately notifies the Director of DMHDDAD and law enforcement authorities.

5. If law enforcement authorities initiate an investigation into the death of a consumer, the state hospital/community provider staff cooperate with the investigators.

6. If, at any time during an investigation, it appears that a community provider or its staff has failed to protect the health, safety and/or welfare of the consumers in its care, the Investigations Section requests that the Regional Coordinator take immediate steps to protect such consumers, including the removal of the consumer(s) to another community provider, if needed. The Regional Coordinator, or his/her designee, notifies the Investigations Section of actions taken.

7. The Investigations Section completes its *Final Investigative Report* (Attachment B) for all unexplained or suspicious deaths within thirty (30) calendar days following the date of the death or discovery of the death.

8. The Investigations Section requests a copy of the consumer's death certificate from the Division of Public Health. This copy may not be reproduced or released outside the Division of MHDDAD. If the cause of death differs from the report submitted by the state hospital/community provider, the case is reopened and the DMHDDAD Medical Director is notified to review the case.

9. The Investigations Section distributes a Draft *Final Investigative Report* for review to the Division Director, Assistant Division Director of Program Development and Operations, Medical Director, and Legal Services. The reviews (Attachment C) are given to the Investigations Section within seven (7) calendar days of receipt. A summary of the reviews is distributed to the Division Director who provides final approval of the *Final Investigative Report* within 14 calendar days of receipt.

10. If there is a compelling reason why the Investigations Section cannot complete the investigation within thirty (30) days, a *Request for Extension* form (Attachment D) must be filled out and submitted to the Division Director outlining the reasons and giving an expected completion date. Such requests must be received by the Division Director at least five (5) calendar days prior to report due date. The Division Director may establish a new deadline, not to exceed thirty (30) calendar days.

11. The Investigations Section delivers the *Final Investigative Report* to the Director of Regional Operations within three (3) calendar days of completion of the report. The Director of Regional Operations distributes the *Final Investigative Report* to the state hospital/community providers and Regional Coordinator.

B. Investigation of all other deaths

1. The state hospital/community provider designates qualified staff, who has been trained to do investigations, to conduct investigations of all other deaths.

2. The investigation includes:

- Interviewing consumers, staff and other involved parties;
- Reviewing all related documentation; and
- Collaborating with outside agencies, as applicable.

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3. All investigations completed by the state hospital/community provider are thorough and must address, at a minimum, those items identified in the *Protocol for Investigations* (Attachment A).

4. If, at any time during the investigation, evidence of criminal conduct is discovered, the state hospital/community provider immediately notifies law enforcement authorities and notifies the Investigations Section.

5. If law enforcement authorities initiate an investigation into the death of a consumer, the Regional Hospital Administrator (RHA) or community provider administrator ensure that their staffs cooperate with the investigators.

6. If, at any time during an investigation, it appears that the community provider or its staff has failed to protect the health, safety and/or welfare of the consumers in its care, the Regional Coordinator takes immediate steps to protect such consumers, including the removal of the consumer(s) to another community provider, if needed. The Regional Coordinator, or his/her designee, notifies the Investigations Section of actions taken.

7. The state hospital/community provider completes and submits a *Final Investigative Report* (Attachment B) to the Investigations Section. These reports are submitted via fax, mail or electronically within thirty (30) calendar days following the date of the consumer's death or discovery of death.

8. If there is a compelling reason why the state hospital/community provider cannot complete the investigation within thirty (30) days, a *Request for Extension* form (Attachment D) is filled out and submitted to the Investigations Section outlining the reasons and giving an expected completion date. Such requests must be received by the Investigations Section at least five (5) calendar days prior to report due date. The Investigations Section may establish a new deadline, not to exceed thirty (30) calendar days.

9. When state hospitals/community providers receive autopsy reports, a copy is provided to the Investigations Section on the same day of the receipt of the report.

10. The Investigations Section requests a copy of the consumer's death certificate from the Division of Public Health.

C. Investigation of all other Category I and II critical incidents

1. The Investigations Section investigates all Category I critical incidents, unless the Investigations Section determines that the provider should conduct the investigation. This determination is made within 3 hours of receipt of the initial report, and is based on the type of incident and the investigation history of the provider.

2. The state hospital/community provider designates qualified staff who are trained to do investigations to investigate all Category II critical incidents.

3. The investigation includes, at minimum:

   - Interviewing consumers, staff and other involved parties;
   - Reviewing all related documentation; and
   - Collaborating with outside agencies, as applicable.

4. All investigations completed are thorough and must address, at a minimum, those items identified in the *Protocol for Investigations* (Attachment A).

5. If, at any time during an investigation, it appears that the community provider or its staff has failed to protect the health, safety and/or welfare of the consumers in its care, the Regional Coordinator takes immediate steps to protect such consumers, including the removal of the consumer(s) to another community provider, if needed. The Regional Coordinator, or his/her designee, informs the Investigations Section of actions taken.

6. If, at any time during the investigation, evidence of criminal conduct is discovered, the investigator immediately notifies law enforcement authorities.

7. If law enforcement authorities initiate an investigation into a critical incident of a consumer, state hospital/community provider staff cooperate with the investigation.

8. The results of investigations of the following incidents involving the following residents are reported to the Regional Hospital Administrator within five (5) working days of the incident:

   - Skilled nursing facilities- Allegations of abuse, neglect or exploitation; injuries of unknown origin; misappropriation of resident property; or
   - ICF/MR-Allegation of abuse or neglect with injury requiring treatment beyond first aid; time-out or restraint resulting in injury requiring treatment beyond first aid; death not related to course of illness or underlying condition; allegation of rape or sexual assault.

9. The investigator completes and submits a *Final Investigative Report* within thirty (30) calendar days following the date of the incident or discovery of the incident to the Investigations Section.

10. If there is a compelling reason why the investigation cannot be completed within thirty (30) days, a *Request for Extension* form (Attachment D) is filled out and submitted to the Investigations Section outlining the reasons and giving an expected completion date. Such requests are received by the Investigations Section at least five (5) calendar days prior to report due date. The Investigations Section may establish a new deadline, not to exceed thirty (30) calendar days.

11. The Investigations Section delivers the *Final Investigative Report* to the Director of Regional Operations within three (3) calendar days of completion of the report. The Director of Regional Operations distributes the *Final Investigative Report* to the state hospital/community provider and Regional Coordinator.

D. Administrative Review

1. State hospitals/community providers perform a review of all the *Final Investigative Reports* completed by the state hospital/community provider. The review includes, at a minimum:

   - Reading the *Final Investigative Report*;
   - Reading all accompanying documentation;
   - Requiring and ensuring the completion of any incomplete or missing documentation; and
   - Signing off as the administrative reviewer on the *Final Investigative Report*.

2. The Investigations Section reviews all *Final Investigative Reports* completed by state hospital/community providers for content, thoroughness of the investigation, and demonstration that conclusions were based on the evidence available. The review includes, at a minimum:

   - Reading the *Final Investigative Report*;
   - Reading all accompanying documentation;
   - Requiring and ensuring the completion of any incomplete or missing documentation; and
   - Completing the *Review of Final Investigative* Report form (Attachment C).

3. For Final Investigative Reports completed by the state hospital/community provider that are deemed inadequate, the Investigations Section returns the report to the state hospital/community provider for corrections. The state hospital/community provider has three (3) business days to complete and return the Final Investigative Report with corrections.

4. The Director of Investigations or his/her designee reviews all *Final Investigative Reports* completed by the Investigations Section. The review includes, at a minimum:

   - Reading the *Final Investigative Report*;
   - Reading all accompanying documentation;
   - Requiring and ensuring the completion of any incomplete or missing documentation; and
   - Signing off as the administrative reviewer on the *Final Investigative Report*.

5. The Division Medical Director conducts and documents a review of all consumer death files.

E. Corrective Action Plans and follow-up

1. Upon completion and review of *Final Investigative Report* the Investigations Section notifies the state hospital/community provider of the need for a Corrective Action Plan (CAP). The Regional Coordinator is also notified.

2. A CAP (Attachment E) must be submitted to the Investigations Section for all critical incidents where problematic issues were noted within 14 calendar days of notice from the Investigations Section.

3. The Investigations Section accepts or makes recommendations for changes to the CAP with input from the Regional Coordinator. The Regional Coordinator is responsible for follow-up to ensure that all corrections are made.

4. For CAPs that are not completed successfully by contracted providers, the Regional Coordinator coordinates appropriate contract actions with DMHDDAD Legal Services.

F. Computer Data Entry

1. DMHDDAD maintains a consumer death and critical incident database in order to identify patterns and to perform trend analyses.

2. Each state facility designates one or more persons to be responsible for entering the Final Investigative Report deadline into the database.

3. The Investigations Section enters the date the Final Investigative Report was received from the state/hospital community providers into the database.

Contractors and their subcontractors shall maintain consumer records, report to and participate in the information systems of the Department, and supply any data requested by the Regional Office, Division or Department for the analysis of services in the state. Records and data shall be maintained in accordance with all applicable Federal and State statutory and regulatory requirements, as well as any other requirements of the Department, Division or Regional Office. Failure to meet any or all of the requirements may result in any or all of the consequences stipulated and authorized in Paragraph 113 (Notification of Breach, Contract Termination and Liquidated Damages) of the contract with the Division/Regional Office.

I. CONSUMER RECORDS

A. All contractors and their subcontractors (except for contractors and subcontractors providing Prevention Services) shall maintain consumer records including but not limited to relevant demographic, clinical, programmatic and physical health information regarding each person served.
B. Contractors and their subcontractors shall maintain current, detailed, organized behavioral health records in accordance with all applicable Federal and State statutory and regulatory requirement for each consumer sufficient to reflect and disclose the quality, quantity, appropriateness, and timeliness of services performed pursuant to the Contract with the Division/Regional Office.
C. Records for each consumer shall be maintained in such form and with such content as may be specified from time to time by the Department, the Division, the Regional Office and applicable accreditation, licensure or certification bodies. During any audit or review of records, at least 90 percent of the records subject to review should reflect accurate documentation of consumer clinical records

II. STATEWIDE INFORMATION SYSTEMS

A. Mental Health, Mental Retardation, Substance Abuse Information System (MHMRIS)

1. The MHMRIS is a unified system for the collection of data regarding consumers served by providers of Mental Health, Developmental Disabilities and Addictive Diseases Services in community settings. It allows for the systematic input and processing of data and the production of routine and non-routine reports meeting the basic informational needs of providers, Regional Offices, Division and the Department.

2. Contractors (except for contractors and subcontractors providing Prevention Services) must enter data into MHMRIS for all services they and their subcontractors provide that are funded in whole or in part under the Contract with the Division/Regional Office. The *MHMRIS User's Manual* is issued at the initial session of the New Provider's Training Class conducted by the Division of MHDDAD. Data entry must be in accordance with the *MHMRIS User Manual*, and be accurate and complete, reflecting the most recent information available in consumers' clinical records. All data additions and releases must be entered into the MHMRIS in a timely manner and no later than the eighth calendar day of the following month. Additions and releases after that date may result in a delay or non-payment of the monthly payment to the contractor.

Contractor must submit a Quarterly Data Attestation Form, included in the Appendix of this section, by the end of each fiscal quarter, certifying that its records of consumer enrollments active on the last day of the first month of that quarter have been compared to the data in MHMRIS and the data in MHMRIS are accurate. If the data are not accurate, the contractor shall provide a plan for the immediate action to correct the data in MHMRIS and a plan for maintaining data accuracy.

3. Contractors submitting *Forms 1261 and 1262, Monthly Income and Expense Report*, included within the Appendices of Section VI of this Manual, early should have entered all addition and release data into the MHMRIS current to the date of submission.
4. Assistance with the MHMRIS is available to contractors and their subcontractors from the following sources, all located within the Georgia Department of Human Resources at 2 Peachtree Street NW, Atlanta, GA 30303:

    a. Community Information Systems Support Coordinator, Division of MHDDAD, at (404) 657-6428 for help in:
        - Ordering *Document Direct* software to facilitate print reports from Infopac
        - Utilizing the MHMRIS' *Facility Data Structure* feature to capture service enrollments
        - Remote Access Control Facility Identification (RACF ID) passwords
        - Access to MHMRIS data reports using View Direct, Document Direct and/or the GTA Electronic Reporting System website (http://ebill.gagta.com)
        - Training on MHMRIS
    b. Information Technology Coordinator for Mental Health, DHR Office of Technology and Support, at (404) 463-2183 for assistance with:
        - File Transfer

B. Performance Measurement and Evaluation System (PERMES)

1. PERMES is a comprehensive outcome evaluation and measurement system, the purpose of which is to improve the performance and accountability of the state's public MHDDAD system. To do this, PERMES measures outcomes utilizing data collected through MHMRIS, special collection techniques on scores generated using specified clinical assessment instruments, the PERMES consumer and family surveys, as well as other sources.
2. Contractors and subcontractors will be required to submit data on scores generated through the clinical assessment instruments utilized by PERMES. These instruments include the *Daily Living Activities Scale* (DLA and the *Child and Adolescent Functional Assessment Scale* (CAFAS) Protocols for using these instruments and reporting scores derived from these instruments will be released periodically by PERMES. Contractors and subcontractors must comply with the conditions of these protocols, and submit data in accordance with the protocols and reporting instructions.
3. PERMES Surveys require no direct action from or by contractors and their subcontractors. However, contractors and their subcontractors must make their facilities and consumers available to PERMES survey teams.

C.Fee-For-Service Pilot

For Fiscal Year 2006, providers of Mental Health and Addictive Disease services and supports should expect to submit a monthly summary report of services, unduplicated numbers of

consumers per service, and units delivered per service. The prescribed reporting process will be released early in Quarter 1 of FY2006.

Developmental Disabilities Planning List Operational Protocol

It is the responsibility of the Regional Office to manage planning lists. This responsibility cannot be transferred to the Intake and evaluation vendor. This management includes working

closely with the Intake Team to make determinations at the time of intake as to the level of need and eligibility for the short-term planning list, long-term planning list or immediate placement.

A. When it is determined that an individual is eligible for MR/DD services however there is no funding available or limited funds are available to partially serve the consumer, the Regional Office will place the consumer on the short term or long term planning list using the following criteria:

a. Short Term Planning List Criteria

1. No caretaker
2. Caretaker is unable to provide care
3. Person is at risk of harm
4. And in all situations noted, the issue cannot be resolved by any other means

b. Long Term Planning List Criteria

1. The person is eligible for MR/DD services with documented need for services
2. The person is not in imminent risk of harm

c. It is the responsibility of the Intake team to maintain and track determinations made by the Regional Office. The data for the planning lists must be current and accessible to the regional office at all times. Such tracking shall document:

1. The name of the individual/applicant
2. The name and contact information of the individual's/applicant's legal representative if not self and next of kin
3. The date of the determination
4. The name of the regional staff person who made the determination
5. If on the short term planning list, the date of referral to the Support Coordination agency
6. A scheduled date for follow up
7. Documentation of any subsequent contacts and their results

d. For individuals placed on the short-term planning list, tracking will include documentation of contacts made by the Support Coordinator per the targeted intervals as defined in the intake process on the Individualized Service Plan; additionally, documentation will include a scheduled date for the purposes of follow-up that is six (6) months post the initial screening date. Contacts with the Support Coordinator will facilitate access to other supports and services outside those funded through DHR and to monitor if the individual's need for services has become any more acute and therefore document if there is need for more immediate supports.

e. For individuals placed on the long-term planning list, tracking will include a scheduled date for the purposes of follow-up that is twelve (12)-months post the initial screening date to determine if the individual's need for services has become any more acute at that time.

1. Each consumer on the long term planning list will have his/her status formally evaluated by the intake and evaluation vendor on an annual basis. The results of this evaluation will be forwarded to the regional office and the designated support coordinator if one is assigned to the consumer. The regional office will notify the individual in writing of the results of the evaluation and the individual's status on the planning list. In the letter the regional staff will make themselves available to meet

with the consumer and/or his/her family if requested.

Division	POLICY	NO:
MHDDAD		11.500
		ORIGINAL EFFECTIVE DATE: July 1, 2002
		REVISION EFFECTIVE:

SUBJECT: Contract Dispute Resolution for MHDDAD Service Provider Contracts Managed Through Regional Offices

REFERENCE: Official Code of Georgia Annotated 37-1-1, 37-1-20(b)(3) and 37-2-1(b)

I. PURPOSE

To establish a process and procedure to be followed when a provision(s), term(s) or condition(s) of a contract with the Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD) and a contractor(s) is disputed.

II. APPLICABILITY

Applies to contracts for direct consumer services managed by the Division of Mental Health, Developmental Disabilities and Addictive Diseases through its Regional Offices.

III. DEFINITIONS

A. Contractor – a provider of services under contract with the DMHDDAD.

B. DMHDDAD – the Division of Mental Health, Developmental Disabilities and Addictive Diseases.

C. Regional Coordinator – an employee of the department who acts as the department's agent and designee to manage community and hospital services for consumers of disability services within a mental health, developmental disabilities, and addictive diseases region established in accordance with Code Section 37-2-3.

D. Regional Executive Director – the state employee who is the administrator in charge of regional office operations until such time as a Regional Coordinator and Regional Services Administrator are duly employed in the region.

E. Regional Office – a DMHDDAD of the Department of Human Resources office created pursuant to Code Section 37-2-4.1 Such office shall serve as the entity for the administration of disability services in the region.

F. Regional Services Administrator – an employee of the department who, under the supervision of the regional coordinator, manages the purchase or authorization of services, or both, for consumers of disability services, the assessment or coordination of services, and ongoing monitoring and evaluation of services provided within a mental health, developmental disabilities, and

addictive diseases region established in accordance with Code Section 37-2-3.

IV. POLICY STATEMENT

It is the policy of The Division of Mental Health, Developmental Disabilities and Addictive Diseases to ensure that all parties engaged in the provision of consumer service(s) by contract with the DMHDDAD through the Regional MHDDAD Offices understand and mutually agree to the specifications and expectations of the contract. The DMHDDAD, through the Regional MHDDAD Offices, will expeditiously attempt to resolve any contract dispute.

The Contractor and the Regional MHDDAD Office will take steps to immediately resolve certain disputes that may arise under the contract. Contract dispute resolution is intended to provide an informal forum for addressing issues including, but not limited to, contract interpretation or clarification of the parties' duties and responsibilities. It is not, however, intended to apply, nor shall it be used, when a party to the contract has officially asserted a claim for breach or failure to perform as provided for in the contract. Parties to the contract dispute resolution process are encouraged to use appropriate means of communication and contact in order to resolve any dispute(s) as quickly as possible.

V. PROCEDURES

When a contract dispute occurs, the contractor shall continue to perform all services as specified in the contract, while taking the following steps to resolve the issue(s) in dispute:

A. The Contractor shall file a notice of dispute in writing to the Regional Services Administrator (or the Regional Executive Director on an interim basis until such time as the Regional Services Administrator is duly employed by the Division) in the applicable Regional MHDDAD office. This notice shall indicate the nature and basis of the dispute and designate a contact person with whom the Regional staff will work to resolve the dispute.

B. The Regional Services Administrator shall review the notice and attempt to address the concerns or issues contained therein. The Regional Services Administrator shall respond, in writing, to the written notice with a finding no later than five (5) business days after the date of receipt of the notice.

C. If the Regional Services Administrator is unable to resolve the dispute, the Contractor may submit a written request to resolve the dispute to the Regional Coordinator (or in the absence of a duly employed Regional Coordinator, the Division Director). The written request shall specify the matter(s) to resolve, the attempt(s) made to resolve the dispute and the reason(s) the previous resolution(s) did not work.

D. The Regional Coordinator (or Division Director pursuant to section V. C.) shall review the materials and respond in writing with a finding(s) and recommendation(s) no later than five (5) business days after the date of receipt of the review materials. The finding(s) and recommendation(s) of the Regional Coordinator (or Division Director) shall be final.

Disputes that cannot be resolved and that result in a party not performing under the terms and specifications of the contract may serve as a basis for officially asserting a claim for breach or failure to perform as provided for in the contract.

Division: **MHDDAD**

POLICY

No. 3.106
Effective Date: July 1, 2002
Annual Review Month May

SUBJECT: Consumer Complaints and Grievances

REFERENCE: OCGA § 37-2-5.2(a)(9); § 37-2-11.2; § 30-5-1 et seq.

I. PURPOSE

The purpose of this policy is to ensure a process for filing consumer complaints and grievances and to provide guidance for receiving, considering and resolving consumer complaints and grievances filed with the Division of Mental Health, Developmental Disabilities and Addictive Diseases and/or DMHDDAD service providers.

II. APPLICABILITY

This policy applies to the Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD) State and Regional Offices, service providers having a contract or letter of agreement with the Department of Human Resources through the DMHDDAD and it's Regional Offices, regional state hospitals, and state-operated community service providers. The procedures established by this policy shall not supplant the complaint procedures governing complaints alleging violation(s) of a patient's rights under the Rules and Regulations for Patient's Rights, Chapter 290-4-6 or a client's rights under the Rules and Regulations for Client's Rights, Chapter 290-4-9.

III. DEFINITIONS

A. Consumer – A person who has been or is a recipient of disability services. (O.C.G.A. § 37-1-1 (5); O.C.G.A. § 37-2-2 (3))

B. Provider – A person or entity having a contract or letter of agreement to provide DMHDDAD services, a DMHDDAD regional state hospital, a state-operated community service provider and/or an Outdoor Therapeutic Program.

C. Regional Office – A Division of MHDDAD of the Department of Human Resources office created pursuant to Code Section 37-2-4.1. Such office shall serve as the entity for the administration of disability services in a region.

IV. POLICY STATEMENT

It is the policy of the Division of Mental Health, Developmental Disabilities and Addictive Diseases to ensure that consumers, representatives, guardians, individuals, associations, or agencies involved with the delivery or receipt of disability services may file and have reviewed complaints and grievances. All complaints and grievances shall be heard promptly, investigated appropriately, and where possible, resolved informally. No person shall be retaliated against or be denied services for filing a complaint or grievance.

V. PROCEDURES

A. DMHDDAD Regional Offices and providers shall designate staff to receive, process, investigate, monitor and report consumer complaints and grievances.

B. All consumer complaints and grievances made to DMHDDAD Regional Offices must:

a. Be taken, whether received via telephone, in person, by referral, or by other telecommunications medium;
b. Identify the provider, where applicable;
c. State the nature of the complaint or grievance;
d. Identify the consumer(s) involved and/or the name of the person filing the complaint or grievance;
e. Be reduced to writing, either by the complainant or the person taking the complaint or grievance at the Regional Office; and
f. Be kept on file in accordance with DMHDDAD Records Retention Policy Number 14.800.

C. The Regional Office shall follow the steps below in addressing consumer complaints and grievances made directly to the Regional Office:

a. **Step 1 -** Make initial determination: Upon receipt of a complaint or grievance, the Regional Office must determine whether the complaint or grievance will be processed by the Regional Office or whether the complaint or grievance will be referred to another agency or entity for resolution. As an example, complaints or grievances involving certain Social Security benefits issues should be referred to the Social Security Administration.

i. If the complaint or grievance will be processed by the Regional Office, proceed to paragraph "b" below.

ii. If the complaint or grievance will not be processed by the Regional Office, the Regional Office staff will notify the

complainant, by telephone and in writing, within five (5) business days of receipt of the complaint or grievance of the reason(s) the Regional Office cannot properly address the complaint or grievance. Whenever possible, the Regional Office staff will provide sufficient information to the complainant for referral to the appropriate entity for relief.

b. The Regional Office, where possible, must determine if the matter under complaint or grievance is the subject of pending or current litigation by asking the complainant.

   i. If the complaint or grievance is the subject of current litigation or if a response cannot be obtained, the Regional Office shall immediately contact the Division's Office of Legal and Risk Management Services for guidance.
   ii. If the complaint or grievance is not the subject of current litigation, proceed to Step 2.

c. **Step 2** - Make secondary determination: The Regional Office must determine whether the complainant has filed the complaint or grievance first with the provider, if applicable, and what, if any, resolution was suggested.

   i. If the complainant has filed the complaint or grievance with the provider, but:

      1. The complainant is dissatisfied with the provider's suggested resolution; or
      2. The complainant does not want to or refuses to communicate with the provider; or
      3. The provider has not taken any action regarding the complaint or grievance; or
      4. No provider is involved in the complaint or grievance, then
      5. The Regional Office will review/investigate the complaint or grievance and attempt(s) to resolve the complaint or grievan

   ii. If the complainant has not filed the complaint or grievance with the provider, the Regional Office shall:

      1. Advise the complainant of the need to first exhaust all remedies available through the provider. The Regional Office must still record the complaint or grievance and forward it to the provider.
      2. Inform the complainant that the complaint or grievance will be promptly forwarded to the provider and that the

provider will contact the complainant to resolve the matter.

3. Follow up with the provider within five (5) business days of the referral to verify that the complaint or grievance has been or is in the process of being resolved. The Regional Office is not prohibited from reducing the time period for this follow up. In no case, however, shall the follow up occur more than five (5) business days from the referral date.

iii. If the Regional Office discovers, upon its follow up of the referral of the complaint or grievance to the provider, that:

1. No process for resolution has commenced, the Regional Office will record the reason(s) why no process has begun. The Regional Office will then conduct a review of the complaint or grievance pursuant to this policy by proceeding to Step 3; or
2. The provider has begun to review the complaint or grievance and is working toward a resolution, the Regional Office will record that information and request that the provider forward to the Regional Office notice of resolution of the complaint or grievance. The Regional Office need not take additional action unless the circumstances demand further inquiry/action.

d. **Step 3 -** Regional Office Review/Investigation: The Regional Office shall conduct and complete a review of the complaint or grievance within five (5) business days of receipt of the complaint or grievance or within five (5) business days of the date it is determined the provider has not begun a resolution process as outlined in Section V.C.c.iii.1. above.

i. Review elements: The Regional Office's review/investigation shall, at a minimum, provide that:

1. Informal resolution, where appropriate, will be utilized;
2. Investigative methods deemed most suitable to determine the facts will be utilized. Such methods may include, but are not limited to, personal interviews, telephone calls, and/or review of documents and correspondence. The reviewer/investigator shall have access to all documents and records and personnel relevant to the investigation;
3. Confidential information will be protected against unauthorized disclosure(s);
4. Conflicts of interest will be avoided and where discovered, immediately corrected; and

5. Whenever appropriate or necessary, signed releases of information will be obtained.

ii. Extensions: The Regional Coordinator may grant an extension of this time frame upon request and upon a showing of good cause, such as the complexity of the issue(s) or if fact gathering warrants additional time. If the Regional Coordinator approves an extension, the Regional Office shall notify the complainant in writing of the extension and indicate the time frame within which the review will be concluded. Where applicable, a copy of the notice of extension shall also be forwarded to the provider. An extension shall not exceed twenty (20) business days from the date of receipt of the complaint or grievance.

e. **Step 4** - Findings/Resolution: The Regional Office shall notify the complainant in writing, within five (5) business days of the completion of the complaint or grievance review/investigation, of the finding(s) and the recommendation(s) for resolving the complaint or grievance. Such notification of findings/resolution shall include an explanation of the process by which the consumer may appeal the findings/resolution of the Regional Office. A copy of the findings must be kept on file along with the complaint or grievance and a copy must be forwarded to the provider, if applicable.

f. **Step 5** - Appeal: Where a complainant is dissatisfied with the resolution proposed by the Regional Office, the complainant may request that the Regional Office forward a copy of the complaint or grievance, all relevant material, and all proposed resolution(s) to the MHDDAD Division Director or the Division Director's designee. A complainant is not precluded from filing an appeal directly to the Division Director or the Director's designee, in which case the Division Director or designee will contact the Regional Office to request copies of all material(s) relevant to the complaint or grievance. The Division Director or designee's review of the complaint or grievance shall be completed within ten (10) business days of receipt of the appeal and all relevant materials. The Division Director or designee will provide a resolution for the complainant that shall be final. A copy of the final resolution shall be forwarded to the Regional Office and, if applicable, to the provider. The Regional Office and where applicable, the provider, must maintain on file a copy of the final resolution of all complaints and grievances.

D. All providers shall submit to the Regional Office a copy of the provider's policies and procedures for receiving, considering, and resolving consumer complaints and grievances. Each provider's policies and procedures should address, at a minimum, the following:

a. Instructions on how a consumer complaint or grievance may be filed with the provider.
b. A description of the review/investigation process for resolving the complaint or grievance, including reasonable applicable time frames and extensions, if permitted, for review by and response from the provider.
c. A requirement that the provider's complaint and grievance policies be filed with the Regional Office.
d. Directions for the complainant to appeal to the Regional Office when a satisfactory resolution is not reached at the provider level.
e. Directions for the complainant to appeal to the Division of Mental Health, Developmental Disabilities and Addictive Diseases when an unsatisfactory decision is made by the Regional Office.
f. Display prominently at each service location the name, title, location, hours of availability, and telephone number (a 1-800 number is preferred for multi-county locations) of the designated person whose responsibility it is to accept and oversee the process of any complaint or grievance on behalf of the provider.
g. Maintain copies of all consumer complaints and grievances received and reviewed by the provider and complaints and grievances reviewed by the Regional Office, copies of appeals made to the MHDDAD Division Director, notices of extension of the time to conduct and complete a complaint or grievance review/investigation, and copies of all "final" rulings or resolutions.
h. Ensure that each consumer receives information explaining the provider's complaint and grievance procedure, including appeals, in a manner that is understandable to the person served.
i. Ensure that the filing of a consumer complaint or grievance will not result in retaliation or barriers to service.
j. Ensure that all provider staff receive training in the provider's consumer complaint and grievance policy and procedure, including the duty to assist consumers in reporting complaints and grievances.

E. Reporting of complaints and grievances

a. Providers must submit quarterly reports of all consumer complaints and grievances to the Regional Office by the 15th of the month following the quarter being reported. Reporting should include complaints and grievances received directly as well as those received through the Regional Office. The reports must include:

i. Types and dates of all complaints and grievances;
ii. Originator of complaints and grievances;
iii. Complaints and grievances new in the current quarter and those unresolved from previous quarters;
iv. Of resolved complaints and grievances, the numbers of substantiated and unsubstantiated complaints and grievances;
v. Days to resolution for each complaint or grievance;

vi. Disability and program involved; and
vii. Identified systems issues and corrective measures taken, if any.

b. Regional Offices must submit quarterly reports of all consumer complaints and grievances to the Division by the last day of the month following the quarter being reported. These reports shall include a summary of provider reports and additional data from complaints and grievances processed by the Regional Office. The reports must include summary data regarding:

i. Number of complaints and grievances for the quarter, new and unresolved;
ii. Types of complaints and grievances;
iii. Originators of complaints and grievances;
iv. Of resolved complaints and grievances, the numbers of substantiated and unsubstantiated complaints and grievances;
v. Days to resolution for each complaint or grievance;
vi. Disabilities and programs involved;
vii. Summary of provider improvement activities related to findings about complaints and grievances; and
viii. Summary of regional improvement activities related to findings about complaints and grievances.

Prepared by:
Legal and Risk Management Section

Approved by:
Karl Schwazkopf, Director

DIVISION MHDDAD

POLICY

NO. 11.400
EFFECTIVE DATE 01-16-94
ANNUAL REVIEW MONTH: July
REVISION EFFECTIVE: July, 2001

SUBJECT: EMERGENCY PREPAREDNESS AND DISASTER RESPONSE

REFERENCE: Official Code of Georgia Annotated Chapter 37-1-20; HCFA Regional Office Protocol for Conducting Full Reviews of State Medicaid Home and Community-Based Services Waiver Program, Version 1.2

I. PURPOSE

To delineate regional planning unit responsibilities for the safety and care of consumers in the preparation for and response to emergency or disaster situations.

II. APPLICABILITY

Applies to the Regional Planning Units of the Division of Mental Health, Mental Retardation and Substance Abuse.

III. DEFINITIONS

A. Emergency conditions - an unexpected situation or sudden occurrence of a serious and urgent nature that demands immediate attention. Severe weather conditions such as ice storms, snow accumulations, hurricanes, floods or torrential rains which impede or prohibit the continuation of normal activities.

B. Disaster - an occurrence causing widespread destruction and distress. Severe weather conditions such as ice storms, snow accumulations, storms or torrential rains, depending upon severity may be classified as either emergencies or disasters. Hurricanes, tornadoes, floods, droughts and earthquakes are usually classified as disasters.

C. Preparedness - activities, programs and systems that exist prior to an emergency and are used to support and enhance response to an emergency or disaster. Planning, training and coordinating with other agencies would be preparedness activities.

D. Response - involves activities and programs designed to address the immediate and short- term effects of the onset of an emergency or disaster. Response activities includes direction and control, warning, and

evacuation.

POLICY STATEMENT

It is the policy of the Division of Mental Health, Mental Retardation and Substance Abuse that the Regional Planning Units be prepared to take an active role in ensuring current consumers are safe and receiving needed services and supports during an emergency or disaster. In addition, regions shall have a crisis mental health, mental retardation and substance abuse response system in place to ensure communities and individuals affected by the emergency or disaster are provided the needed support, outreach, and crisis counseling services.

PROCEDURES

A . The Regional Planning Unit is designated by the Division as the lead organization to coordinate and oversee local emergency/disaster response of MHMRSA consumers. The Regional Planning Unit shall have a written emergency preparedness and disaster response plan that specifically addresses the responsibilities listed below, and should identify the position within the Regional Planning Unit responsible for each activity. The emergency and disaster plans will be reviewed and updated annually or more frequently if needed. A copy of the plan and any updates shall be submitted to the Division's Special Assistant for Emergency Management. The Regional Planning Unit responsibilities include:

1. Acting as liaison between the region, DHR and other state and federal agencies;
2. Obtaining information for the assessment of need and the impact of the emergency or disaster;
3. Requesting assistance if the region lacks the capacity to meet the emergency/disaster response needs;
4. Ensuring good communication between all parties involved in the emergency/disaster;
5. Obtaining needed support for the direct services providers and agencies responding to the emergency/disaster;
6. Designating a lead agency from its pool of providers to act as the single point of contact to coordinate the emergency/disaster response activities for each county within the region and all the region's providers;
7. Requiring each of the region's providers to have a written emergency/disaster procedure and response plan.

B. The Regional Planning Unit shall ensure that each service provider and subcontractor has an adequate written emergency and disaster response plan and shall complete an annual review of each service provider's plan. The Regional Planning Unit will ensure that the region's service providers and subcontractor's emergency/disaster response plans conform to the guidelines established by the Division, outlined in Appendix A of this policy, and include the following:

1. Evacuation plans for current service sites

2. Contingency plans for the continuation of services to consumers during an emergency/disaster which include mechanisms for back care would pose a threat to consumers health and welfare
3. Plan for assisting with the community emergency/disaster response efforts such as outreach, crisis counseling, debriefing and referrals
4. Delineation of staff responsibilities during a disaster
5. Plan for communications during an emergency/disaster

C. The lead agency, **among service providers,** is designated by the Regional Planning Units from its pool of providers and acts as the single point of contact to coordinate the emergency or disaster response activities for each county within the region and all of the region's providers. The lead agency will be responsible for mobilizing the emergency/disaster efforts in the county to include:

1. Designation of the emergency/disaster coordinator for the county plus and alternate
2. Assessment and determination of service need
3. Mobilization and deployment of staff
4. Provision of outreach, crisis counseling services to victims, survivors and rescue worker
5. Coordination of services with other social services agencies with emergency/disaster management entities.

D. The lead agency should incorporate the responsibilities outlined above in the emergency or disaster procedure and response plan required of all service providers. The plan should follow the guidelines outlined in Appendix A of this policy and be updated annually or more frequently if needed. A copy of the plan and any updates should be submitted to the Regional Planning Unit for their keeping and review.

Division MHDDAD | **POLICY** | **NO: 9.102**

Revised Effective Date: 07/01/03

SUBJECT: Requests for Waivers of the Standards for Community Mental Health, Developmental Disabilities and Addictive Diseases

REFERENCE: Official Code of Georgia Annotated 37-2-4

I. POLICY STATEMENT

It is the policy of the Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD) to provide a process for the waiver of standards contained in the Provider Manual for Community Mental Health, Developmental Disabilities and Addictive Diseases Providers Under Contract with the Division of Mental Health, Developmental Disabilities and Addictive Diseases so that when the enforcement of one or more of these standards creates an undue hardship or barrier to the provision of a specific service, DMHDDAD may waive compliance with the requisite standard(s) for a limited period of time. The waiver request process assures a continuing commitment to consumer health and safety, compliance with requirements of external funding and regulatory entities, and accreditation/certification requirements.

II. APPLICABILITY

This policy is applicable to State and Regional Offices of the Division of Mental Health, Developmental Disabilities and Addictive Diseases.

III. DEFINITIONS

None

IV. PROCEDURES

DMHDDAD state and regional managers work in concert to consider and respond to requests for waivers of standards contained in the Provider Manual for Community Mental Health, Developmental Disabilities and Addictive Diseases Providers Under Contract with the Division of Mental Health, Developmental Disabilities and Addictive Diseases. The process for requesting approval of waivers of standards is as follows:

A. A provider, consumer, family member, advocate, or other interested party may request of the DMHDDAD Regional Coordinator that a standard be waived when the standard creates an undue hardship or barrier to providing or accessing a needed service.

B. Within five (5) days after receiving a waiver request, the DMHDDAD Regional Coordinator submits the waiver request, along with his/her recommendations related to the request, to the DMHDAD Director.

If the request is for the waiver of a standard related to a Department of Human Resources (DHR) professional designation listed below, the waiver request must be accompanied by a completed "Request for Waiver of Standards MHP/DDP/SAM/SAP/MHC Designation" form (Attachment 1), including the recommendation and affirmation of competency signed by the provider's Director, Clinical Director, and a licensed professional in the area appropriate to the work of proposed MHP/DDP/SAM/SAP/MHC. The DMHDDAD Regional Coordinator forwards the completed form, along with the waiver request, to the DMHDDAD Director.

1. Mental Health Professional (MHP)
2. Developmental Disabilities Professional (DDP)
3. Substance Abuse Professional (SAP)
4. Substance Abuse Manager (SAM)
5. Mental Health Clinician (MHC)

C. The DMHDDAD Director approves or disapproves the requested waiver after involving appropriate DMHDDAD staff in reviewing the request as documented on the state office review form (Attachment 2).

D. The DMHDDAD Director informs the appropriate DMHDDAD Regional Coordinator of the decision to approve or disapprove the waiver request, including the rationale for the decision, within thirty (30) days after receiving the request.

E. The DMHDDAD Regional Coordinator communicates the DMHDDAD Director's decision to the party making the waiver request within five (5) days after becoming aware of the DMHDDAD Director's decision.

F. The DMHDDAD Regional Coordinator tracks the originator, organization name, date, nature, time to resolution, and disposition of all waiver requests and submits information as requested by DMHDDAD.

G. The provider must maintain on file, a copy of all approved waiver requests and have such waiver(s) available for review.

Attachment 1: Request for Waiver of Standards (Provider Request form)
Attachment 2: Division State Office Review of Waiver Request form

Sections/Office/Unit Responsible for Policy Development/Review:
Consumer Protection, CQI and Monitoring Section

Approved by:
Karl Schwarzkopf, Director
October 21, 2003

REQUEST FOR WAIVER OF STANDARDS **Policy 9.102 Attachment 1**
MHP/MHC/DDP/SAP/SAM DESIGNATION

To: _____ Region: _____
(Regional Coordinator)

From: _____ Contact: _____
(Provider agency applying for waiver) (Agency contact person)

Request waiver of standard(s) related to ( ) MHP ( ) MHC ( ) DDP ( ) SAP ( ) SAM

Staff Member for whom waiver is requested: _____

Justification for request:
(Why does the agency need this person to be a MHP/MHC/DDP/SAP/SAM?)
_____
_____
_____

Waiver Period Requested: _____ through _____
(12 month maximum)

Describe what the agency is doing to ensure sufficient MHP/MHC/DDP/SAP/SAM level staff to meet agency needs without requesting waivers for staff members that do not meet the minimum qualifications:
_____
_____
_____

What education, training, experience, and unique qualifiers does this person have that suggests he/she has the competencies to serve as a MHP/MHC/DDP/SAP/SAM at this time? (include comparison to MHP/MHC/DDP/SAP/SAM qualifications) _____
_____
_____

What is this staff member doing to acquire the education, training and experience required for MHP/MHC/DDP/SAP/SAM designation without a waiver of standards? _____
_____
_____

Recommendations: I hereby recommend approval of the requested waiver. Based on my personal observation of this individual's work, I affirm that he/she is competent to perform the duties of the designation sought (MHP, MHC, DDP, SAP or SAM). Furthermore, I give my assurance that approval of this waiver will not adversely effect the safety and welfare of consumers. The staff member will receive clinical supervision by a licensed professional, as specified in the current Provider Manual.

_____ _____ _____ _____
Agency Director Date Clinical Director Date

_____ _____ _____
Licensed Professional License Held Date

DIVISION STATE OFFICE REVIEW OF: REQUEST FOR WAIVER OF STANDARDS MHP/MHC/DDP/SAP/SAM DESIGNATION **POLICY 9.102 Attachment 2**

Request waiver of standard(s) related to ( ) MHP ( ) MHC ( ) DDP ( ) SAP ( ) SAM

Region Requesting Waiver of Standards: _____

Individual for whom waiver is requested: _____

Agency for which individual works: _____

Is there evidence that the provider agency has a need for this individual to be given MHP/MHC/DDP/SAP/SAM designation? Describe:_____

_____

_____

Does the agency have a plan for ensuring sufficient numbers of MHP/MHC/DDP/ SAP/SAM level staff to meet its service needs? Is the agency following its plan? Describe: _____

_____

_____

_____

Does the individual for whom a waiver is requested, meet most of the criteria for MHP/MHC/DDP/SAP/SAM designation? Is the individual currently working toward meeting requirements for MHP/MHC/DDP/SAP/SAM designation? Describe:

_____

_____

_____

Does the Agency's Clinical Director recommend this individual for MHP/MHC/ DDP/SAP/SAM designation and affirm the individual's competence? _____

Does an appropriate licensed professional recommend this individual for MHP/ MHC/DDP/SAP/SAM designation and affirm the individual's competence? _____

Division staff recommendation: ( ) Approve ( ) Disapprove
Rationale:_____

_____

_____

_____ _____
Division Staff Signature Date

(Draft and attach a memorandum to the Regional Coordinator from the Division Director, relaying a decision in keeping with your recommendation. Forward the draft memorandum and all forms to the Division Director for review.)
Decision of Division Director: ( ) Approve ( ) Disapprove

_____ _____
Division Director Signature Date

SPOE
Service Entry and Linkage Requirements

A region that claims to have or contracts for a Single Point of Entry shall have the following Core Functions. This Single Point of Entry may be for all ages and disabilities for the total region, for any specific age group(s) or disability(s), or for any specific catchment area(s).

Service Expectation 1:

All persons residing within a region are served by the SPOE, including transient, out of catchment, and homeless persons.

Benefits/Outcomes:

The SPOE follows the Division of MHDDAD Policy entitled "Determination of Regional Responsibility/Maintenance of MHDDAD Services" issued April 5, 1999.

Service Expectation 2:

A telephone number(s) is operational and published so that all persons may call toll free at all times (24/7) to request information about services, screening for eligibility, referral, and crisis service.

Benefits/Outcomes:

At least one (1) toll free number is dedicated to the SPOE.
The number is published.

- The line is answered 24 hours a day, seven days a week by trained staff.
- Screening for eligibility means to determine that the caller represents someone who can be served by regional resources.

Service Expectation 3:

Cross regional recognition exists for the point of entry. The SPOE number is publicized and available to community agencies, organizations, current consumers, etc.

Benefits/Outcomes:

Screening for eligibility means to determine that the caller represents someone who can be served by regional resources.

- The local telephone directory,
- Local emergency rooms,
- Police stations,
- Sheriff's posts,
- Public and private service provider agencies and offices,
- State facility system,
- The public at large

Service Expectation 4:

Sheriffs, judges, other applicable law enforcement and other potential referral sources are aware of and utilize the system of SPOE.

Benefits/Outcomes:

- There is evidence that the SPOE offers a forum at least one time per year that provides law enforcement personnel (police, sheriffs), judges, provider agencies, and other potential referral sources an opportunity to understand services available, ask questions or bring issues to the table.
- The SPOE provider can demonstrate satisfaction with the services provided by the SPOE. Assessment of satisfaction of referral sources, service providers and consumers should be conducted at least annually.

Service Expectation 5:

Telephone crisis intervention services exist, including crisis lines and telephone support available for clients currently enrolled in services.

Benefits/Outcomes:

The SPOE has the following capacity:

- The ability to quickly triage, manage and direct or refer all calls.
- A staffed crisis intervention line by which urgent matters can be handled for any and all persons.
- A staffed telephone line by which clients in services may bring issues requiring counseling or support

Service Expectation 6:

The SPOE has the capacity to provide or arrange for avenues of communication for the following persons:

- the hearing impaired
- the blind
- non-English speaking person.

Service Expectation 7:

Transportation to a needed service is offered or arranged by the SPOE with heavy reliance upon natural supports.

Benefits/Outcomes:

An assessment of the transportation needs will be done when transportation is required. The SPOE has the capacity to negotiate or arrange for safe transport of the consumer as required.

Service Expectation 8:

The SPOE coordinates and tracks data related to service use for all entry points of the service system of care.

Benefits/Outcomes:

The SPOE maintains a tracking document of client movement into service provider agencies.

Service Expectation 9:

The SPOE will offer choice when provider choice is available.

Benefits/Outcomes:

If there are two or more providers authorized by the region who offer the level of service required by the consumer, the consumer will be offered choice.

Service Expectation 10:

The SPOE insures that all of its entry points use consistent eligibility screening and referral criteria.

Benefits/Outcomes:

- Common (statewide) age and disability based criteria will be used by the SPOE to screen for need and eligibility for services.
- Protocols or decision trees used to refer clients to particular services can be clearly demonstrated.

Service Expectation 11:

The SPOE coordinates by contract or agreement the use of local community inpatient beds (if the Region contracts for local hospital beds.

Benefits/Outcomes:

The SPOE maintains a daily utilization log for contracted local community inpatient beds.

Service Expectation 12:

Screening for intensive services is available:

- Crisis stabilization unit(s)
- Local contracted hospital bed use
- Screening for state hospital beds, including TIC's
- Other less intensive crisis services.

Benefits/Outcomes:

- The criteria used for screening and referral is overt, clear and consistent.
- The SPOE can demonstrate how the decision to refer for Temporary and Immediate Care is criteria-based.

Service Expectation 13:

The SPOE will assure linkage to the appropriate level of care.

- Linkage is made to the next appropriate level of care for admission to and discharge from the state hospital, local contracted hospital bed use, the crisis stabilization program and crisis group home.
- Discharge planning is assured from services offered by providers who have agreements, memorandums of understanding, or contracts with the SPOE.

Benefits/Outcomes:

The SPOE maintains a daily utilization log for the client admission to and discharge from the following regional provider services including, but not limited to:

- The state hospital facility system.
- Local contracted hospital bed use.
- The crisis stabilization program.
- Residential detox services.

The SPOE is able to demonstrate how linkage to ongoing services is assured based on client need.

Service Expectation 14:

Linkage is assured for all persons referred into and out of the regional network of services.

Benefits/Outcomes:

The SPOE incorporates a method of identifying those persons placed outside the 'region of responsibility' as well as identifying those persons placed within the region from another 'region of responsibility'.

Service Expectation 15:

The SPOE follows up all bypasses of this system.

Benefits/Outcomes:

- The SPOE has a mechanism for identifying those persons served by providers wh bypassed the SPOE.
- The SPOE will work to achieve or is able to demonstrate (Region chooses) to demonstrate that at least 85% of all persons who are in state funded or authorized provider services were screening by the SPOE.

Service Expectation 16:

In all cases, the activities of the SPOE will be compatible with federal and state laws, rules and regulations.

Benefits/Outcomes:

- Practices of the SPOE demonstrate compatibility with all federal and state laws, rules and regulations.
- Staff working within the SPOE demonstrate evidence of understanding including, but not limited to:
  - Federal substance abuse law.
  - State MHDDAD law.
  - Rules regarding patients/clients rights.
  - ADA law and rules
  - EMTALA
  - Standards of the Division of MHDDAD as written in the Provider manual for the Division of MHDDAD.

DIVISION: MHMRSA

POLICY

NO. 7.103
EFFECTIVE DATE: July 1, 2001
ANNUAL REVIEW MONTH May
REVISION EFFECTIVE: 06-28-01

SUBJECT: Region of Responsibility Determination

REFERENCE:

I. PURPOSE

The purpose of this policy is to establish guidelines for determining the region of responsibility, i.e., the region responsible for services delivered to a consumer and for the associated costs.

II. APPLICABILITY

This policy is applicable to the Regional Mental Health, Mental Retardation and Substance Abuse Boards and Regional Offices and state-operated facilities.

III. DEFINITIONS

None

IV. POLICY STATEMENT

It is the policy of the Division of Mental Health, Mental Retardation and Substance Abuse that for each consumer, except those identified in Section IV-A below, a region of responsibility will be established and maintained in all service records. The region of responsibility is the MHMRSA regional board responsible for the publicly-funded portion of all provided services, including cost of care and associated hospital Days of Active Client Enrollment (DACE). This policy addresses determination of and documentation of region of responsibility and associated issues. Nothing in this policy should be interpreted to reduce in any way the obligation of regional boards to deal with crisis/emergency situations that occur within their regions and to respond to essential consumer service needs while residency and responsibility questions are being resolved. Further, nothing in this policy should be interpreted to constrain the freedom of consumers to seek services wherever they wish regardless of residency and responsibility determinations.

V. PROCEDURES

At the time a consumer enters services, the region of responsibility shall be assigned based on the consumer's region of residence. If a consumer enters services via hospital admission, the region of residence recorded by the hospital shall be the presumed region of responsibility and shall remain so until evidence to the contrary is provided by the

regional office. While most commonly the consumer's region of residence is the region of responsibility, it is recognized that some circumstances lead to a change. The guidelines provided below should be used in making such determinations.

A Memorandum of Understanding (MOU) is required whenever a consumer receives services in a region other than the region of responsibility, including occasions when movement between regions is initiated for services-related reasons such as hospital discharge planning. The region initially responsible for the consumer's services shall obtain the agreement of both regions and document their agreement in an MOU. Among other factors, the MOU should designate the region of responsibility, service and funding responsibilities, crisis resource responsibility, regional staff contacts with consumer/family, reporting of incidents, and monitoring/oversight. Any transfers of funds associated with region-of-responsibility MOUs will be accomplished through the Budget Allocation System (BAS).

A. Exceptions

1. The following consumers will not be assigned a region of responsibility, and no region will be charged for the cost of services:

    a. Out-of-state consumers, i.e., those who are admitted to a hospital or crisis stabilization program for whom discharge planning will involve the consumer returning to another state for continued services.

    b. Consumers admitted to state institutions from Department of Corrections (DOC) or Department of Juvenile Justice (DJJ), prisons or YDCs, who will be returning to the DOC or DJJ facility upon hospital discharge.

B. Guidelines for Determining Region of Responsibility

1. For the purpose of this policy each consumer shall be assigned a region of residence expect those identified in Section IV-A above.

    a. Consumers residing in long term care facilities such as nursing homes, with no plans to return to another residence, are considered residents of the region in which the long term care facility is located.

    b. Consumers considered homeless because they do not have a residence or a permanent place to live will be assigned a region of residence based on the region in which they are currently staying. For example, a person staying at a Salvation Army lodge or living under a bridge will be assigned a region of residence based on the location of the Salvation Army lodge or the bridge. If even such temporary living situations do not exist, then the region of residence shall be the region in which the consumer became involved with the service delivery system.

The consumer's region of residence shall be the region of responsibility until subsequent events affect that determination.

2. For an adult consumer (age 18 and up) the region of responsibility is the consumer's region of residence. For a consumer under age 18, the region of residence of the custodial parent(s) or legal guardian is the region of responsibility, regardless of the location of the minor's residence. When a county Division of Family and Children Services (DFCS) office retains legal custody of a consumer, whether adult or minor, the region in which the DFCS office is located is the responsible region.

3. If a consumer moves from one region to another for reasons unrelated to any MHMRSA service needs (including placement in a long term care facility such as a nursing home), the new region of residence becomes the new region of responsibility. Region of responsibility changes at the time of relocation even when this occurs in the middle of a hospitalization or residential placement. An MOU is required only if the consumer continues to receive services in a region other than the new region of responsibility.

4. If a minor consumer's custodial parent/legal guardian relocates to another region, the region in which the new residence is located becomes the region of responsibility, regardless of the location of the minor's residence. If a minor consumer's custodial parent/legal guardian relocates out of state, the region of responsibility remains the last region in Georgia in which the parent(s)/guardian resided.

5. If a consumer moves to another region for reasons that, by definition, are intended to be temporary (foster home, nursing home for rehabilitation, a halfway house, a trial visit), the original region of responsibility remains the region of responsibility. An MOU is required for the duration of the temporary stay.

6. When a region places a consumer in another region for services, the region making the placement remains the region of responsibility and an MOU is required. If a consumer independently obtains services in a region other than his/her region of residence, the region of residence is the region of responsibility, and an MOU is required.

7. If a consumer is discharged from a state hospital and re-admitted from a location other than the original region of responsibility, the circumstances of the discharge and placement may affect the region of responsibility for the re-admission. If the consumer was discharged to a location intended to be temporary, the original region of responsibility remains the responsible region. If the consumer voluntarily moved to a location intended to be permanent, the new residence determines the region of responsibility even if the consumer has been in the new region only a short time.

8. Other extenuating circumstances regarding establishing the region of responsibility may be mutually agreed upon by the affected regions.

C. Steps to Take when the Regions Cannot Agree Upon Region of Responsibility

1. When a consumer's region of responsibility cannot be determined at the regional level, formal request for a determination of region of responsibility will be submitted to the Division Director for resolution by the region currently bearing responsibility for the consumer. (Note: For consumers who are in state hospitals, if regions have not reached agreement concerning the region of responsibility within a timeframe appropriate for a hospital discharge decision, the hospital is authorized to seek the assistance of the Division's Medical Director.)

2. The Division Director will then review the matter to determine which region is responsible for the consumer.

Guidelines for Termination of Services Due to Refusal to Pay

In accordance with Paragraph 202.C.4. of the Division's contracts with providers, Contractors agree Ato establish and collect co-payments and deductibles in accordance with a sliding fee scale. Such sliding fee scale must be submitted to and approved by the Regional Office.≅ The sliding fee scale should be part of an equitable fee collection system. Such a sliding fee schedule would not be applicable to individuals with Medicaid benefits who are receiving Medicaid reimbursable services. In addition, for individuals with other third party payors, the sliding fee schedule should only be applied appropriately to any remaining liabilities once third party payment has been received. *Consumers may be billed on 100% liability and/or third party payors for the actual cost for all services rendered, unless such billing is prohibited or excluded by federal or state law or regulation or insurance agreements. **Under no circumstances may consumers covered under contract with the Division be refused services because of an inability to pay.** The provider must develop and maintain a pricing structure for services that includes all indirect and direct costs. The pricing structure must be clear, legally imposed and designed to ensure fairness. Consumers must be notified upon entry into services of the fee schedule and payment liability that will be incurred as a result of their care. The provider may refuse services if the consumer refuses to pay, or refuses to give the information necessary to determine the payment liability, only after compliance with these basic guidelines. Consumers must also be informed, in advance, of any subsequent changes in the fee schedule.

Refusal to Pay

While providers have the right and responsibility to collect legally recognized debt, in exercising this right, the health and safety of the consumer must not be jeopardized. If a consumer refuses to pay an administrative and clinical review of the situation must be conducted prior to any denial of services. Consumers who refuse to provide information concerning their financial status or third party payors, may also be considered unwilling to pay.

a. The administrative review should include consulting with the consumer about any change in financial status and if appropriate a re-determination of the appropriate percentage of the consumer's liability. The consumer must be given the opportunity to pay any new amount. Additional circumstances pertaining to non-payment should be discussed with the consumer.
b. If no resolution is reached, a clinical review must be conducted by a psychiatrist designated by the agency in conjunction with the consumer's case coordinator/case manager to determine mental/diagnostic status or other factors that might attribute to non-payment and to determine whether the consumer is in acute crisis or at risk of inpatient care and/or dangerous to self or others, based upon the information available. The consumer must be notified of the conference and if he/she chooses to participate, it must be scheduled to accommodate his/her particular situation (i.e., access to transportation, etc.).
c. If the clinical review finds that the consumer is not dangerous to self or others, not in acute crisis nor at risk of inpatient care, a review must be conducted by a specified member of the agency's board. **Consumers who are dangerous to themselves or others, in acute crisis, or at risk of inpatient care must be served regardless of payment status.**
d. If services are to be denied ***due to clinical or administrative findings as specified in these guidelines***, the written decision must be signed by the agency Director and Board Chair, and forwarded to the affected Regional Office. Notification of termination of services and the reason(s) for the action must be made through face-to-face or telephone

contact with the consumer as well by mail. The written notification will include the statement that the consumer may receive services if he/she agrees to pay the assessed liability fee or provides the information needed to assess the consumer's liability, or if the consumer experiences an acute crisis.

e. The decision-making process associated with the termination of services must be thoroughly documented in the consumer record, including the findings of the administrative and clinical reviews.

It is expected that a provider will have its own more detailed policy pertaining to fees, fee schedules and termination of services due to refusal to pay. These guidelines should be evident in the agency policy(s).

****Consumers, for the purposes of this policy, not only applies to individuals receiving direct services but also to parents, legal guardians and/or other parties determined to be responsible for payment.***

	Department of Human Resources **Directives Information System**	**Index: POL1244** **Effective: 10/13/1999** **Review: 07/01/2004** **Page 1 of 2**

SUBJECT: External Entities Audit Standards and Sanctions

POLICY

The policy of the Department of Human Resources is to ensure that those non-federal entities which receive funds from the Department conform to the standards and requirements imposed by federal and state law and by DHR Contracts. Sanctions are imposed on those entities that do not comply with the standards and/or audit requirements.

A. Authority

O.C.G.A. 50-20-1 through 50-20-8 as amended, 1998 Legislative Session
Single Audit Act Amendments of 1996 (PL 104-156)

B. References

OMB Circular A-133
CFR Title 45, Part 74.60 et seq of CFR
CFR Title 7, Part 277.17 entitled "Audit Requirements"
Standards for Audit of Governmental Organizations, Programs, Activities and Functions

C. Applicability

All of the Department of Human Resources

D. Definitions

1. Non-Federal Entity: A state, local government, or a nonprofit organization.
2. Sanctions: Penalties imposed by the Department on those fund recipients who do not abide by their contract requirements for audit reports and fail to comply with state law regarding timeliness. Sanctions may include: reimbursements being withheld, contracts being canceled, recoupment of funds, and denial of further contracts with the Department for a period of 12 months.

E. Responsibilities

The Director of the Department of Human Resources' Office of Audits is responsible for issuing and updating procedures to implement this policy. The procedures are indexed at PRO1244.

F. History

Replaces Department of Human Resources Administrative Policy and Procedures Manual, Part V. A. 4., "Auditing/Reporting/Sanctions for Nonprofit Organizations Required by the Governor's Executive Order Dated May 27, 1997," effective July 1, 1997, and Part V. A. 5., "Standards for Audits Purchased by DHR Agencies and Local Entities as Required by the Single Audit Act Amendments of 1996," effective July 1, 1997.

G. Evaluation

none

H. Authentication

__(signed by Audrey W. Horne)___ _____10/13/1999__

Commissioner Date

	Department of Human Resources **Directives Information System**	**Index: PRO1244** **Revised: 07/01/2002** **Review: 07/01/2004** **Page 1 of 5**

SUBJECT: External Entities Audit Standards

PROCEDURE

Entities that contract with the Department must meet certain financial reporting requirements. These requirements are defined in: the Single Audit Act Amendment of 1996; OMB Circular A-133; Contract Provisions; DHR Policy; and Title 50, Chapter 20, Sections 1 through 8 of the Official Code of Georgia Annotated. The requirements vary according to the dollar amount expended by the entity during its accounting year. The Office of Audits and the DHR Programmatic Division have certain responsibilities that are delineated below. Several words and phrases are used in these procedures that may have meaning that is special to these procedures. These words and phrases are defined below.

The address for the DHR Office of Audits is:

DHR Office of Audits
Two Peachtree Street, NW
Suite 26.425
Atlanta, Georgia 30303-3142

The address for the State Department of Audits is:

State Department of Audits and Accounts
Professional Practices Division - Suite 214
254 Washington Street SW
Atlanta, Georgia 30334-8400

1. Definitions

Budget Category: A numbering system used for budget and accounting purposes that corresponds to a specific program name. Numbers reduce chances of confusion with similar program names.

Contractor's Fiscal Year: The 12-month accounting period established by the entity as its business year, which is on file with the U.S. Internal Revenue Service as the basis for filing required tax and Tax Exempt Status Returns.

Entity: An organization receiving funds from DHR exclusive of DHR field offices.

Expense Category: A numbering system corresponding to a list of specific services within a Budget Category, where the amount of funds used to pay for the service are recorded for accounting purposes.

Independent Auditor:

-A Certified Public Accountant (CPA); or

-A Registered Public Accountant (RPA) licensed on or before December 31, 1970; or
-A government Auditor located outside the staff or line management function of the unit under audit.

To be independent, the auditor's relationships with the auditee is of such an "arm's length" nature so as to preclude any **appearance** of bias, or any obligation to or interest in the auditee, its management or its owners. Relationships or combinations of relationships with the auditee must not create any conflict of interest that impairs the auditor's integrity and objectivity with respect to the audit engagement. It is inappropriate in some circumstances for auditors to perform both audit and non-audit services for the same client.

Major Program: A federally funded program determined by the auditor to be a major program in accordance with OMB circular A-133, Section_.520 or a program defined as a major program by a federal agency or pass-through entity in accordance with Section_.215(c).

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized primarily for profit; and uses its net proceeds to maintain, improve, or expand its operations.

Program: A grouping of activities and resources to accomplish a mission with specific goals and objectives. Some programs have names, some have numbers, and some have both. Usually programs are budgeted by number for ease of tracking and to reduce potential confusion. Budget categories can and are considered to be programs. Federal programs are considered to be those activities that are or can be assigned a single number in the Catalog of Federal Domestic Assistance (CFDA). When no CFDA number is assigned, all federal awards from the same agency made for the same purpose are to be combined and considered one program. Throughout this procedure, the term "program" refers either to a named activity or an activity that is numbered.

Public Entity: Includes, but is not limited to: state and local governments and their instrumentalities; authorities; county Boards of Health; Community Service Boards; and District Attorneys (judicial circuits) operating Child Support Enforcement programs through contracts with DHR.

Schedule of State Awards Expended: A schedule arranged by state program name and contract number that reflects revenues, expenditures, or expenses and amounts owed to and due from each state organization. Amounts listed for each program should include federal funds that pass through state organizations to the entity.

2. Requirements Prior to Contract

Prior to executing a contract between the DHR and a non-profit organization, the organization furnishes a previous year's audit. If the entity has been in existence for less than a year, then they furnish unaudited financial statements. If no audit or unaudited financial statements are on record with DHR, the following procedure is followed:

-The contracting division or Office of DHR requests such audit or financial statements as part of its negotiation or solicitation process.
-The entity furnishes an audit report (or unaudited financial statements, if appropriate) to the DHR Office of Financial Services, Contract Section, as a part of its contract package.

-When it is received, the financial information is forwarded to the Office of Audits for a compliance review. The Division of Mental Health, Mental Retardation, and Substance Abuses' Regional Boards submit requested financial audits and statements directly to the Office of Audits for compliance review.
-The Office of Audits reviews the information and determines compliance with O.C.G.A. Section 50-20-1 through 50-20-8, as amended, 1998 Legislative Session.
-The Office of Audits notifies the Contracts Section of the Office of Financial Services or the Regional Board of the results of its review. For instances of non-compliance with requirements, the omitted items are specified.

3. Requirements of Contractors

The financial reporting requirements vary depending on the amount of state and/or federal funds expended by the entity during its fiscal year.

3.1. Entities expending $300,000 or more in federal funds

All entities expending $300,000 or more in federal funds during their fiscal year comply with: the provisions of the Single Audit Act Amendments of 1996 and their implementing regulation - OMB Circular A-133; with contract provisions; and with DHR Policy. Non-profit organizations also comply with the provisions of the O.C.G.A. Annotated, Section 50-20-1 through 50-20-8, as amended, 1998 Legislative Session. Audits of nonprofit organizations also include a "Schedule of State Awards Expended."

These entities obtain a single entity-wide audit of their financial records performed by an independent auditor. The audit covers all financial activities for the fiscal year and is conducted in accordance with Generally Accepted Government Auditing Standards issued by the Comptroller General of the United States.

Audits for public entities include, for those contracts that were completed during the audit period, a "Statement of Revenues and Expenditures Compared to Budget," presented by program name or contract name and number. This statement is presented by contract name and number for the entire contract period. Audits of public entities also include a "Schedule of State Awards Expended."

The entity files two copies of the independent auditor's report with the Director, DHR Office of Audits, within 180 days after the end of the organization's fiscal year. Additionally, private nonprofit organizations submit one copy of the report to the State Department of Audits and Accounts within the same time period. If an extension of the time period is desired, the State Department of Audits (for private nonprofit entities) or the DHR Office of Audits (for public entities) may waive the requirement for completion if a request is made that shows good cause. The waiver is for an additional period of not more than 90 days, and no such waiver is granted for more than two successive years to the same entity. A plan of corrective action for all deficiencies disclosed in the audit report is submitted with the audit report.

3.2. Entities expending $100,000 or more in state funds

All entities expending $100,000 or more in state funds during their fiscal year comply with contract provisions and DHR policy. Nonprofit organizations also comply with the provisions

of the O.C.G.A. Annotated, Section 50-20-1 through 50-20-8, as amended, 1998 Legislative Session. Audits of nonprofit organizations also include a "Schedule of State Awards Expended."

These entities obtain an entity-wide audit of their financial records performed by an independent auditor. The audit is conducted in accordance with Generally Accepted Auditing Standards issued by the American Institute of Certified Public Accountants and the financial statements are prepared in accordance with generally accepted accounting principles. Audits for public entities include, for those contracts that were completed during the audit period, a "Statement of Revenues and Expenditures Compared to Budget," presented by program name or contract name and number. This statement is presented by contract name and number for the entire contract period. Audits of public entities also include a "Schedule of State Awards Expended."

The entity files two copies of the independent auditor's report with the Director, DHR Office of Audits, within 180 days after the end of the organization's fiscal year. Additionally, private nonprofit organizations submit one copy of the report to the State Department of Audits and Accounts within the same time period. If an extension of the time period is desired, the State Department of Audits (for private nonprofit entities) or the DHR Office of Audits (for public entities) may waive the requirement for completion if a request is made that shows good cause. The waiver is for an additional period of not more than 90 days, and no such waiver is granted for more than two successive years to the same entity. A plan of corrective action for all deficiencies disclosed in the audit report is submitted with the audit report.

3.3. Entities expending between $25,000 and $100,000 in state funds

All entities expending at least $25,000 but less than $100,000 in state funds during their fiscal year comply with contract provisions and DHR policy by submitting audited or unaudited financial statements. Nonprofit organizations are also required to comply with the provisions of the O.C.G.A. Annotated, Section 50-20-1- through 50-20-8, as amended, 1998 Legislative Session. Audits or financial statements of nonprofit organizations also include a "Schedule of State Awards Expended."

Financial statements that have been audited include the auditor's report on the financial statements. Audits for public entities include, for those contracts that were completed during the audit period, a "Statement of Revenues and Expenditures Compared to Budget," presented by program name or contract name and number. This statement is presented by contract name and number for the entire contract period. Audits or financial statements of public entities also include a "Schedule of State Awards Expended."

Financial statements that have not been audited include a statement from the president or other responsible official of the organization which states that:

-The financial statements are presented in accordance with generally accepted accounting principles and, if not, the basis used for their presentation;
-The financial statements are prepared on a basis consistent with that of the preceding year, and if not, the respects in which they differ from the preceding year;
-The financial statements of public entities include for those contracts that were completed during the audit period, a "Statement of Revenues and Expenditures Compared to Budget," presented by program name or contract name and number.

This statement is presented by contract name and number for the entire contract period. The financial statements of public entities also include a "Schedule of State Awards Expended."

The entity files two copies of the audit or financial statements with the Director, DHR Office of Audits, within 180 days after the end of the organization's fiscal year. Additionally, private nonprofit organizations submit one copy of the report to the State Department of Audits and Accounts within the same time period. If an extension of the time period is desired, the State Department of Audits (for private nonprofit entities) or the DHR Office of Audits (for public entities) may waive the requirement for completion if a request is made that shows good cause. The waiver is for an additional period of not more than 90 days, and no such waiver is granted for more than two successive years to the same entity. A plan of corrective action for all deficiencies disclosed in the audit report is submitted with the audit report.

4. Role of the DHR Office of Audits

The DHR office of Audits:

-Requests the required audit or financial statements from those entities that have failed to provide them;
-Reviews the audit reports for financial settlement amounts, questioned costs, and findings and recommendations;
-Communicates the dollar amounts of financial settlements to the DHR Office of Financial Services for settlement;
-Requests corrective action plans to preclude recurrence of findings from those entities that have failed to provide them;
-Forwards one copy of the audit report or financial statements to the programmatic Division(s) or Office(s); and
-Notifies the appropriate DHR programmatic Division(s) or Offices(s) of those entities which have not complied with the filing requirements of this policy as well as the DHR Office of Financial Services that will impose the appropriate sanctions.

5. Role of the Programmatic Division(s) or Office(s)

The programmatic Division(s) or Office(s):

-Insures that appropriate programmatic corrective actions are implemented when required by an audit report;
-Reviews audits for compliance with programmatic performance goals;
-Enforces corrective action on repeat findings; and
-Approves or disapproves budget and spending variances.

A. History

Replaces Department of Human Resources Administrative Policy and Procedures Manual, Part V. A. 4., "Auditing/Reporting/Sanctions for Nonprofit Organizations Required by the Governor's Executive Order Dated May 27, 1997", effective July 1, 1997, and Part V. A. 5., "Standards for Audits Purchased by DHR Agencies and Local Entities as Required by the Single Audit Act Amendments of 1996", effective July 1, 1997.

B. Proponency

Office of Audits

Instructions for HIPAA Privacy Rule Forms

Pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), covered entities must maintain, and in some cases provide to individuals copies of, a Notice of Privacy Practices, Authorization(s) for Use or Disclosure of Protected Health Information, and Business Associate Agreements. This packet includes samples of these three documents that you may use as guidance in complying with the Act, as well as the following instructions for each document. However, THESE SAMPLES ARE NOT TO BE CONSTRUED AS LEGAL ADVICE AND NO REPRESENTATION OF LEGAL SUFFICIENCY FOR PURPOSES OF YOUR ENTITY'S COMPLIANCE WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 ("THE ACT") IS BEING PROVIDED. IT IS YOUR RESPONSIBILITY TO ENSURE THAT YOUR ENTITY COMPLIES WITH THE ACT.

Notice of Privacy Practices. Providers must immediately begin to give to all current and new consumers a copy of this form, and ask them to read and sign it. If applicable, the consumer's parent (for minors) or guardian may sign the form on the consumer's behalf. The provider must give a copy of the notice to the person who signed it. If the consumer or parent/guardian declines to sign the form, the provider should still give a copy of the form to the consumer or parent/guardian. Providers must ensure that a copy of the form is maintained in the consumer's clinical record.

Every consumer is entitled to a copy of this form upon request. Therefore, providers should keep a supply of the form available. Parents and guardians may also request a copy.

The provider must ensure that this notice is also posted at all times in a prominent location where it is reasonable to expect individuals who are seeking or receiving services to be able to read the notice.

Authorization for Use or Disclosure of Protected Health Information. This form replaces any form, including **DHR Form 5459**, previously used for the consumer, parent (for minors) or guardian to sign in order to authorize disclosure of the consumer's protected health information. Please immediately destroy all blank copies of other authorization forms that you may have. Providers must begin immediately to use this form to obtain any new authorization(s) for the use or disclosure of information regarding all current and new consumers. Providers must maintain a copy of each fully completed and signed form in the consumer's clinical record. A provider may choose to modify this form, for instance, by adding spaces for the consumer's name and identifying information (kardex type data), or to add the name and contact information of the provider.

Business Associate Agreement

Contracted providers of DHR are Business Associates of DHR as defined in the HIPAA Privacy Rule. As such, they must sign a Business Associate Agreement with DHR.

Business Associate language will be incorporated into the contract template language for all DHR FY '04 contracts.

Providers, as Business Associates of DHR, are required to ensure that their agents and/or subcontractors comply with all Privacy Rule requirements that are applicable to the Provider. Providers will, therefore, enter into Business Associate Agreements with their agents and/or subcontractors who have access to protected health information of individuals served under the provider's contract(s) with DHR.

Providers must retain copies of all Business Associate Agreements for as long as they do business with the agent and/or subcontractor, or for six (6) years, whichever is longer. The Provider will give DHR access to each of its Business Associate Agreements upon request.

NOTE: For written contracts existing as of October 15, 2002, and not renewed or modified by April 14, 2003, the Provider has until April 14, 2004, to enter a Business Associate Agreement with agents and/or subcontractors. **In all other cases**, Providers must obtain signed agreements with all their applicable agents and/or subcontractors **by April 14, 2003**.

Georgia Department of Human Resources
Division of Mental Health, Developmental Disabilities and Addictive Diseases

POLICY
NO: 3.200
Original Effective Date:
04/14/03
Revised Effective Date:
N/A

Policy Subject: Protection of Individually Identifiable Health Information – Compliance with HIPAA Privacy Rules

REFERENCE: 45 CFR Parts 160 and 164; DHR HIPAA Policies 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 15.0, 16.0, and 20.0.

I. POLICY STATEMENT

It is the policy of the Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD) to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and related Department of Human Resources (DHR) policies by establishing the needed procedures and related protocols. HIPAA does not supercede or negate more stringent federal and state laws, rules and regulations.

II. APPLICABILITY

The DHR is a covered entity under HIPAA and the Privacy Rule, and the DMHDDAD is covered as a part of the Department. This policy is therefore applicable to any entity that is a part of the division, including the state office, regional offices, state operated DMHDDAD hospitals and any state operated community programs. All employees, agents, trainees, volunteers and contractors of the DMHDDAD shall abide by the DMHDDAD and DHR policies and all federal, state and local laws regarding the disclosure and use of protected health information. DMHDDAD service providers who are under contract or have a letter of agreement with the DHR through the DMHDDAD and its Regional Offices are business associates of the DMHDDAD (see definition of business associate below) and must comply with applicable provisions of the Privacy Rule.

III. DEFINITIONS

A. Authorization – Permission by a consumer or a person legally authorized to consent on his/her behalf, for the release or use of protected health information.

B. Business Associate - A person or entity who is not a member of the covered entity's work force and who, on behalf of the covered entity, performs or assists in the performance of a function or activity involving the use of individually identifiable health information.

C. Covered Entity – A health care provider, health plan, or health care clearinghouse that transmits any health information in electronic form in connection with a HIPAA transaction; Georgia DHR is a covered entity.

D. De-identified Information – Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.

E. Disclosure – Release, transfer, provision of access to, or divulging in any other manner, information by an entity to persons or organizations outside of that entity.

F. Accounting of disclosures – A history of when and to whom disclosures of protected health information are made for purposes other than treatment, payment, and health care operations.

G. Health and Human Services (HHS) – The federal government department that has overall responsibility for implementing HIPAA.

H. Health Insurance Portability and Accountability Act of 1996 (HIPAA) – A Federal law that allows persons to qualify immediately for comparable health insurance coverage when they change their employment relationships. Title II, Subtitle F, of HIPAA gives HHS the authority to mandate the use of standards for the electronic exchange of health care data; to specify what medical and administrative code sets should be used within those standards; to require the use of national identification systems for health care consumers, providers, payers, and employers; and to specify the types of measures required to protect the security and privacy of personally identifiable health care information. Also known as the Kennedy-Kassebaum Bill, the Kassebaum-Kennedy Bill, K2, or Public Law 104-191.

I. Individually Identifiable Health Information (IIHI) – Any information, including demographic information collected from an individual, that is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, and identifies the individual; or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. IIHI contains some or all of the following elements:

1. Name
2. All Address Information
3. E-Mail Addresses
4. Dates (except year)
5. Social Security Number
6. Medical Record Numbers
7. Health Plan Beneficiary Numbers
8. Account Numbers
9. Certificate Numbers
10. License Numbers
11. Device Identifiers

12. URLs
13. IP Addresses
14. Facial Photographs
15. Biometric Identifiers
16. The initial three digits of the zip code, unless the geographic unit formed by combining all zip codes with the initial three digits contains more than 20,000 people or the initial three digits of all geographic units with fewer than 20,000 people is changed to 000
17. Any other unique identifying number, characteristic, or code

J. Minimum Necessary – When using or disclosing protected health information or when requesting PHI, the process of making reasonable effort to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request.

K. Notice of Privacy Practice – A notice that provides a clear explanation of the covered entity's privacy practices and the privacy rights of consumers regarding their personal health information.

L. Patient-Identifiable Data – Information that relates to a person's physical or mental health, and that contains enough information to identify the particular individual reflected in the information.

M. Person legally authorized to sign: A person authorized by law to give authorization for disclosure of an individual's protected health information. These persons include, for minors, the parent, the court-appointed guardian or the court-appointed custodian; for adults, the court-appointed guardian of the person.

N. Privacy – HIPAA regulations protect an individual's right to the privacy of his or her medical information to keep it from falling into the hands of people who would use it for commercial advantage, personal gain or malicious harm. The HIPAA privacy regulations require providers to obtain a signed authorization to use or disclose PHI.

O. Privacy Coordinator – The individual designated by the Division (DMHDDAD) with responsibility for obtaining and maintaining a working knowledge of the Department's and Division's privacy and security policies and procedures and of the Privacy Rule to respond to HIPAA-related inquiries arising within the Division, provide information regarding the complaint process and maintain adequate documentation of these activities.

P. Privacy Officer – The individual designated by the Department (Georgia DHR) with responsibility for obtaining and maintaining a working knowledge of the Department's privacy and security policies and procedures and of the Privacy Rule to respond to HIPAA-related inquiries arising within the Department, provide information regarding the complaint process and maintain adequate documentation of these activities. Also has responsibility for coordination of Privacy Coordinators and for certain HIPAA-related reporting.

Q. Privacy Rule – Standards for Privacy of Individually Identifiable Health Information, which implements the privacy requirements of the

Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) 45 CFR parts 160 and 164.

R. Protected Health Information (PHI) – All individually identifiable health information (e.g., name, Social Security number, medical record number, etc.) transmitted or maintained by a covered entity, regardless of form.

S. Workforce – Under HIPAA, this means employees, volunteers, trainees, and other persons under the direct control of a covered entity, whether or not they are paid by the covered entity.

IV. PROCEDURES

A. The DMHDDAD shall have a method to allow individuals to exercise their right to request that DMHDDAD amend PHI or a record about the individual in a designated record set used in whole or in part to make decisions about the individual, for as long as DMHDDAD maintains the PHI in the designated record set.

B. DMHDDAD shall develop and communicate to individuals a process for filing complaints about the division's privacy practices or perceived violations of the Privacy Rule standards and implementation specifications. Such process shall include expectations regarding cooperation with investigations regarding complaints and for reporting as required for compliance reviews.

C. DMHDDAD shall document HIPAA privacy policies, procedures and protocols, either on paper or in electronic form. Any change to a policy, procedure or protocol shall be documented. In addition to policies, procedures and protocols, any correspondence or other documents pertaining to the accounting of disclosures by DMHDDAD shall be documented and maintained on file for six years, or longer if required under other applicable laws, regulations or policies.

D. DMHDDAD shall implement policies, procedures and protocol that are designed to comply with Privacy Rule standards and all implementation specifications for PHI. Policies, procedures and protocol shall be reasonably designed and take into account the size and type of activities that relate to PHI undertaken by DMHHDDAD. These policies, procedures and protocols shall:

1. Restrict access and use based on specific roles of members of DMHDDAD's workforce;
2. Establish criteria to limit routing disclosures to minimum necessary to achieve the purpose of the disclosure;
3. Limit requests to other covered entities to what is reasonably necessary for the particular use or disclosure; and

4. Control when staff requests or discloses the entire medical record. There must be specific justification of the need for the entire medical record.

E. DMHDDAD shall mitigate, to the extent practicable, any harmful effect that is known of a use of disclosure of PHI by DMHDDAD or a business associate, in violation of DMHDDAD policies, procedures and protocols or the requirements of the Privacy Rule.

F. DMHDDAD shall permit an individual to request a restriction of disclosures.
1. DMHDDAD does not have to agree with the restriction.
2. If DMHDDAD agrees to the restriction, both DMHDDAD and its business associates shall honor the restriction, until DMHDDAD or the individual terminates the restriction.
3. If the individual terminates the restriction, DMHDDAD may use and disclose PHI as permitted under the Privacy Rule. If DMHDDAD terminates the restriction without the individual's agreement, it may only terminate the restriction with respect to PHI it creates or receives after it informs the individual of the termination.
4. In the case of an emergency treatment situation{ XE "Emergency treatment situation" }, DMHDDAD is allowed to release PHI to the health care provider. DMHDDAD shall request the provider not further use or disclose the PHI.
5. DMHDDAD shall document the restriction to which DMHDDAD and the individual have mutually agreed.

G. DMHDDAD shall develop physical safeguard standards and access controls for PHI it collects and maintains.

H. DMHDDAD shall have sanction policies, procedures or protocols documented so that employees are aware of what actions are prohibited and punishable. Such sanctions shall comply with the HIPAA Privacy Rule standard for sanctions against members of DMHDDAD's workforce who fail to comply with its privacy policies, procedures and protocols. Appropriate sanctions shall be imposed for violations of DMHDDAD's privacy policies and procedures, or related protocols, standards or directives. Sanctions that may be imposed by DHR are cumulative of those that may be imposed by statute or regulation.

I. DMHDDAD shall train all current and newly hired members of its workforce on its privacy policies, procedures and protocols as necessary and appropriate for them to carry out their functions within DMHDDAD, according to a training plan for HIPAA awareness.

J. DMHDDAD shall obtain from business associates reasonable assurances that they will appropriately safeguard PHI disclosed by DMHDDAD and that

agents, employees and subcontractors of the business associates agree to the same conditions applicable to the business associates with respect to such information. DMHDDAD shall include HIPAA compliance requirements in contracts, other written agreements and expressions of understanding, and purchase orders with business associates to whom DMHDDAD discloses PHI.

K. DMHDDAD shall have a written authorization from an individual before using or disclosing PHI for any purpose not otherwise permitted or allowed by the Privacy Rule.

L. DMHDDAD shall keep an accounting of when and to whom disclosures of PHI are made for purposes other than treatment, payment and health care operations, and shall be able to give an accounting of those disclosures to an individual, if requested. Authorizations from an individual to DMHDDAD are included in the information that is to be tracked and accounted for. A disclosure of PHI that does not require an authorization may, in some cases, have a tracking and accounting requirement.

M. DMHDDAD shall establish a means for an individual to access and inspect his/her PHI in a designated record set for as long as DMHDDAD maintains the PHI in the designated record set.

N. DMHDDAD will establish and implement minimum necessary requirements for uses and disclosures of PHI. DMHDDAD shall make reasonable efforts to limit PHI used, disclosed or requested from another covered entity to the minimum necessary to accomplish the intended purpose of the use, disclosure or request.

O. DMHDDAD shall provide adequate notice to individuals of the uses and disclosures of PHI it may make by providing a Notice of Privacy Practices to persons seeking or receiving services. DMHDDAD shall document its compliance with the notice requirements by retaining copies of the notices it issues.

P. If DHR decides in the future to permit the use or disclosure of health information without authorization to a business associate for fund raising purposes, DMHDDAD shall limit such use or disclosure to demographic information about an individual and dates on which health care was provided to the individual. In such event, all fundraising materials shall include a description of the manner in which the individual may opt out of receiving further fundraising communications, and the Division shall take reasonable steps to ensure that such communications are no longer sent to individuals who choose to opt out.

Q. DMHDDAD shall establish standards relating to uses and disclosures, and de-identification and re-identification of PHI it creates, collects and maintains.

R. DMHDAD shall establish standards relating to uses and disclosures of PHI for marketing purposes in the event DMHDDAD should undertake to engage in marketing after the Privacy Rule becomes effective. As of April 14, 2003, DMHDDAD shall not engage in marketing activities within the meaning of the Privacy Rule, pursuant to the policy of DHR.

S. DMHDDAD shall allow authorized revisions of these privacy policies and procedures in response to changes in administrative, operating or programmatic requirements. The DHR Privacy Officer must approve any and all revisions.

T. DMHDDAD shall adopt supplemental internal privacy policies, procedures or protocols where necessary to meet the requirements of specific programs, activities, or federal or state laws and regulations. Such policies, procedures or protocols shall conform to those of the Department and the Privacy Rule and are subject to review by the DHR Privacy Officer.

U. DMHDDAD shall examine its policies, procedures and protocol on an ongoing basis and as necessary revise these to meet requirements of applicable laws and regulations, including the Privacy Rule.

V. DMHDDAD shall designate a Privacy Coordinator as well as a contact person to be responsible for complaints and to provide privacy practice information. The Privacy Coordinator shall obtain and maintain an adequate working knowledge of DHR's and DMHDDAD's privacy and security policies, procedures and protocols and of the Privacy Rule to respond to HIPAA related inquiries arising within DMHDDAD, provide information regarding the complaint process and maintain adequate documentation of these activities. The Privacy Coordinator shall submit reports of privacy related activities periodically to the DHR Privacy Officer and to the Commissioner of the Department upon request.

The Division may appoint Associate Privacy Coordinators at the regional, institutional or other administrative level. Associate Privacy Coordinators shall obtain and maintain a working knowledge of the DMHDDAD's privacy and security policies, procedures and protocols and of the Privacy Rule equivalent to that required of DMHDDAD. Associate Privacy Coordinators must submit monthly summaries of their privacy-related activities to the Privacy Coordinator.

W. Violation of Division and/or Department privacy policies, procedures and protocols shall be communicated to the DMHDDAD Privacy Coordinator.

Violation reports shall include the date of discovery, nature of the violation, a description of any actions taken within the work unit to mitigate harmful effects of the violation and prevent recurrence, and if known, the name and title of the violator, information about the violator's intent and information on previous similar occurrences. Violation reports shall be in writing for documentation purposes, and may be submitted by mail, as attachments to e-mail, by facsimile or other electronic means.

Sections/Office/Unit Responsible for Policy Development/Review:
Legal and Risk Management

Approved:
Karl Schwarzkopf, Director
April 8, 2003

HOSPITAL ADMISSION CRITERIA

Admission to a hospital of the Division of Mental Health, Developmental Disabilities, and Addictive Diseases is based upon specific admission criteria. Referral of a consumer to an emergency receiving facility triggers such an evaluation. Nevertheless, there is a continuing emphasis upon community-based services for adults, children and adolescents. Where such services are appropriate and available, they should be accessed. Regarding a decision to admit, the following elements will also be considered: (a) CMHC (Community Mental Health Center) Referral Information; (b) Physician's Admission Evaluation.

A consumer meets criteria for admission if upon evaluation, he/she demonstrates a disorder of thought or mood which significantly impairs judgment, behavior, capacity to recognize reality, or ability to cope with the ordinary demands of life as per O.C.G.A. 37-3-1 (11) and one or more of the following:

A. Imminent Danger to Self as evidenced by:
   1. Suicidal ideation, threat, plan, intent;
   2. Suicidal gesture or attempt; or
   3. Self-injurious or self-destructive behavior.

B. Imminent Danger to Others as evidenced by:
   1. Homicidal ideation, threat, plan, or intent;
   2. Act or threat of violence or homicide; or
   3. Increase in aggressive behavior.

C. There is an imminent life-endangering crisis due to the person's inability to care for his/her physical health and safety associated with mental illness as evidenced by:
   1. Deterioration in the ability to exercise daily living skills associated with a mental disorder;
   2. Demonstration of impulsive, abusive or provocative behavior associated with deterioration in self-care, hygiene or personal safety; or
   3. Non-participation or chronic refusal to take indicated medications and interventions resulting in relapse and recurrence of psychiatric symptoms or cognitive dysfunction.

ADMISSION CRITERIA

Below are some significant medical conditions that require further evaluation and discussion prior to referral in order to determine if the consumer is appropriate for admission and treatment at this level of care.

Further evaluation and discussion is required if the consumer:

1. Requires highly specialized medical or surgical services, dialysis, or high-acuity nursing care;

2. Requires I.V. fluids, I.V. antibiotics, or hyperalimentation;

3. Requires further evaluation of acute care of chest pain, hypertension or diabetes;

4. Has a diagnosis of delirium or altered level of consciousness;

5. Has an indwelling urinary or other catheter;

6. Has a primary diagnosis of dementia (including Alzheimer's disease);

7. Has infectious/contagious disease (e.g., TB, measles, MRSA, etc.) or wound requiring isolation or procedures to prevent transmission;

8. Has a behavioral condition secondary to traumatic brain injury, which may have related organic, physical, or social disorders? [O.C.G.A. Section 37-3-1: "traumatic brain injury shall not be considered mental illness"];

9. Requires continuous administration of oxygen;

10. Has an acute overdose and may be medically unstable.

Jim Martin, Commissioner
Karl H. Schwarzkopf, Ph.D., Division Director

Georgia Department of Human Resources • Division of Mental Health, Developmental Disabilities and Addictive Diseases
Two Peachtree Street, NW • Suite 22.224 • Atlanta, Georgia 30303-3142 • 404-657-7857

May 20, 2003

Memorandum

TO: DMHDDAD Providers

FROM: Karl H. Schwarzkopf, Ph.D.
Director

SUBJECT: SHARING CONSUMER INFORMATION WITH OTHER PROVIDERS

As a provider of services for the Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD or the "Division"), you are a business associate of the Division and the Department of Human Resources (DHR) under the provisions of the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations (the "Privacy Rule"). Your contract contains terms describing your duties and responsibilities as a business associate.

As a provider, you may be required or asked to participate in activities of the Division such as utilization management, case coordination, health and safety oversight, or evaluations of consumers that are done by another entity or provider which has a contract with DHR or the Division. These other entities or providers are also business associates of DHR. Their activities are conducted under contract with DHR which requires that they maintain consumers' protected health information in compliance with the Privacy Rule, and that they meet the requirements of a business associate of DHR. For your information, all contractors of DHR, even including those who are not considered business associates of DHR under the Privacy Rule, are required by contract to keep consumer information confidential in compliance with federal and state laws and regulations.

It is permissible for you to share consumer information, including protected health information, with these other providers and business associates of DHR, when you are required to do so to meet your own obligations to DHR. If you wish to verify that a particular entity has a contract with DHR, you may ask the entity to provide you with a copy of its contract. You may also call the DHR contracts office at (404) 656-5739 and ask staff to verify that there is a contract with DHR.

If you have any questions about a particular situation or activity, you may contact the Division Privacy Coordinator by telephone at (404) 657-6423, facsimile (404) 657-6424, or by mail to 2 Peachtree Street NW, Room 22.240, Atlanta, Georgia 30303-3142, or you may contact the DHR Privacy Officer by telephone (404) 656-4421, facsimile (404) 657-1123, or by mail to 2 Peachtree Street NW, Room 29.210, Atlanta, Georgia 30303-3142.

KHS/bwc